SASKATCHEWAN

OFFICE OF THE INFORMATION AND PRIVACY COMMISSIONER

INVESTIGATION REPORT H – 2005 -- 002

PREVENTION PROGRAM FOR CERVICAL CANCER

APRIL 27, 2005

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SASKATCHEWAN

OFFICE OF THE INFORMATION AND PRIVACY COMMISSIONER

INVESTIGATION REPORT H -- 2005 – 002

PREVENTION PROGRAM FOR CERVICAL CANCER

I INTRODUCTION

This report deals with the Prevention Program for Cervical Cancer ("the PPCC") operated by the Saskatchewan Cancer Agency ("the Agency"). This program was implemented by the Agency in the summer of 2003. Our examination of the PPCC also entailed consideration of a number of related issues with respect to *The Health Information Protection Act* (HIPA)[1] and its implementation. This report is lengthy chiefly for four reasons:

1. Some 300,000 Saskatchewan women are or will be affected by the PPCC.
2. The personal health information of those women collected, used or disclosed by the PPCC is interlinked with hundreds of family physicians, Saskatchewan Health, the Saskatoon Regional Health Authority and the Regina Qu'Appelle Regional Health Authority.
3. This was the first opportunity for our office to interpret key provisions in this new and complex health information law.
4. Given current trends in health surveillance, we anticipate that there will be other programs that the Agency may implement or contemplate implementing in the future that would involve the same or similar kinds of issues to those presented by the PPCC.[2]

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[1] *The Health Information Protection Act*, S.S. 1999, c.H-0.021 (available online: http://www.qp.gov.sk.ca/documents/English/Statutes/Statutes/D17.pdf) [hereinafter "HIPA"]

[2] *Final Report: The Task Force for Cervical Cancer Screening – A Screening Program for Cervical Cancer*, October 1999, page 14 suggested the cervical cancer screening program could create a model for subsequent provincial screening program development i.e. prostate, colorectal [hereinafter "Final Report"]

I INTRODUCTION (CONT'D)

I undertook this examination of the cervical cancer screening program with a good deal of admiration for the vital work of the Saskatchewan Cancer Agency. The investigation of cancer, co-ordination of cancer treatment, public education and the enhancement of diagnostic, treatment and care services for those residents of Saskatchewan diagnosed with cancer is very important.

I am also mindful that there have been and continue to be many challenges for health information trustees in Saskatchewan seeking to comply with HIPA. The law has only been in force for little more than 18 months. There are, as yet, no regulations. In August, 2004, Saskatchewan Health published draft regulations and invited public input.[3]

There is no comprehensive interpretative material to assist trustees to navigate this new law. Our office has not had the capacity to develop all of the educational materials we think are required. The Agency, like so many other Saskatchewan health information trustees, is anxious to do 'the right thing' in terms of statutory compliance; however, it is handicapped by much uncertainty as to how the Act will be interpreted by our office and perhaps the courts.

Indeed, it is those circumstances that have led us to conclude that our review of the Program should be as thorough and detailed as possible for whatever assistance it may be to the Agency and countless other trustees.

I am convinced that the important issues raised in this investigation cannot fairly be presented as some kind of contest between privacy and cancer prevention. No one should have to choose between one or the other -- Saskatchewan women deserve both.

---

[3] *The Health Information Protection Act Draft Regulations: DRAFT for Consultation.* Policy and Planning Branch, Saskatchewan Health (available online: http://www.health.gov.sk.ca/mc_hipa_reg_draftforconsultation.pdf)

I INTRODUCTION (CONT'D)

Cancer prevention initiatives cannot be successful if they are not supported by Saskatchewan women who participate with a high level of confidence that their privacy will be respected and the confidentiality of their personal health information will be protected. Achieving privacy and confidentiality protection enhances the effectiveness of cancer prevention. The challenge is to find the appropriate balance to ensure that, in Saskatchewan, we can achieve effective cancer prevention but in a way that is respectful of the rights of women.

II EXECUTIVE SUMMARY

The majority of deaths from cervical cancer are avoidable. Saskatchewan medical experts have developed a plan to ensure that all Saskatchewan women between the ages of 18 and 69 are regularly and appropriately tested for cervical cancer and that there is follow-up by the appropriate health professionals.

The plan involves the Saskatchewan Cancer Agency operating the Prevention Program for Cervical Cancer (PPCC). This entails registration information being provided to the PPCC by Saskatchewan Health. The Pap test specimens are collected by the Regina Qu'Appelle Regional Health Authority (RQRHA) and the Saskatoon Regional Health Authority (SRHA) from family physicians. They are analyzed in the laboratories in those regions. The lab test results are then forwarded to the ordering physician. The Agency sends letters to women to advise them of their Pap test results. The Agency sends follow-up letters to encourage women to either take follow-up action or to continue regular testing at appropriate intervals. The PPCC, as it currently operates, features compulsory registration of all women in the target age group. If a woman objects, the Agency will not send correspondence to the women but will otherwise continue to retain her personal health information and use it for PPCC purposes.

II EXECUTIVE SUMMARY (CONT'D)

Our office determined that it was appropriate to review the PPCC to assess compliance with Saskatchewan's new *The Health Information Protection Act* and privacy best practices. We have also received more than 100 complaints from Saskatchewan women about different aspects of the PPCC.

We reviewed all of the appropriate information collection, use and disclosure transactions; have interviewed relevant staff; and undertaken site visits to review administrative, technical and physical safeguards for personal health information. Although our focus was principally the Agency that operates the PPCC, we were also required to consider the role played by Saskatchewan physicians, Saskatchewan Health and the laboratories in the Regina Qu'Appelle Regional Health Authority and Saskatoon Regional Health Authority. Most of our findings relate to the Agency. Since we have not had the same kind of extensive discussions with these other organizations as occurred with the Agency, we have made a minimal number of findings with respect to those organizations. It would not have been fair to make more extensive findings without giving those organizations greater opportunity to make representations. We have however made a number of recommendations for those other organizations that flowed directly from this investigation.

As will be apparent from the specific findings, we have determined that for the most part the PPCC complies with the applicable legislation, *The Health Information Protection Act*. In terms of security for example, we found that the steps taken by the Agency and the laboratories in the two health Regions meet and exceed statutory standards. We have also found that the collection, use and disclosure provisions in HIPA do authorize the collection, use and disclosure activities integral to the PPCC.

We have however identified three significant issues with respect to the PPCC:

- the need for greater transparency;
- the ability of the Saskatchewan Cancer Agency to rely on the deemed consent provision in HIPA; and
- the need for an opt-out mechanism for Saskatchewan women.

II EXECUTIVE SUMMARY (CONT'D)

A. The need for greater transparency

Transparency is an important requirement codified in section 9 of HIPA. Section 9(1) of HIPA provides that an individual has the right to be informed about the anticipated uses and disclosures of the individual's personal health information. By virtue of section 9(2), any trustee that collects personal health information must take reasonable steps to inform the individual of the anticipated use and disclosure by the trustee. Section 9(3) requires that a trustee must establish policies and procedures to promote knowledge and awareness of the rights extended to individuals by HIPA.

In addition, transparency is stressed as a very important feature throughout the Canadian and international literature that concerns cancer surveillance programs.

When the personal health information in question concerns particularly sensitive information such as the cervical health of a Saskatchewan woman, the appropriate degree of transparency should correspond to the sensitivity of that information. In other words, the degree of transparency should be higher than would be the case for many other kinds of personal health information. The Agency has certainly made serious efforts to communicate information about the PPCC to Saskatchewan women.

However, we find these efforts have been inadequate given:

- The sensitivity of the information;
- The feature of compulsory registration with no opt-out; and
- The new practice that allows the Agency to collect and to communicate the results of Pap tests to Saskatchewan women independent of their physicians.

We have concluded that the appropriate degree of transparency has not been achieved in terms of the PPCC.

II EXECUTIVE SUMMARY (CONT'D)

B. The ability of the Saskatchewan Cancer Agency to rely on the deemed consent provision in HIPA

I have determined that there is authority under *The Health Information Protection Act* for the Agency to collect registration information of Saskatchewan women from Saskatchewan Health; cervical health information from the laboratories in the Regina Qu'Appelle Regional Health Authority and the Saskatoon Regional Health Authority, and then to disclose that information to women and their physicians. There is no requirement under HIPA that the women give their express or implied consent to such disclosure. There is no statutory requirement that the wishes of a woman even be taken into consideration by a trustee.

This authority however is contingent on the Agency otherwise meeting the general duties imposed by HIPA on trustees particularly sections 9 and 16. Section 16 requires that the trustee under HIPA have policies and procedures to ensure compliance with HIPA.

C. The need for an opt-out mechanism for Saskatchewan women

Although the PPCC allows a woman to elect not to receive test results and follow-up letters from the Agency and describes this as an "opt-out", I find that this is not a meaningful opt-out as that term is understood in privacy instruments.

I have determined that, although there is no requirement for express consent from Saskatchewan women before their cervical health information can be disclosed as described above, there are important reasons why the Agency should attempt to meet a higher standard. *The Health Information Protection Act* should be viewed as a floor and not as a ceiling.

II EXECUTIVE SUMMARY (CONT'D)

C. The need for an opt-out mechanism for Saskatchewan women (cont'd)

I have determined that any policy requirement to obtain express consent from Saskatchewan women would not be appropriate and would effectively defeat the value of a cervical cancer screening program. I do, however, believe that Saskatchewan women should be empowered by the opportunity to opt-out of the cervical cancer screening program if they so choose.

There are a number of possibilities to create a meaningful opt-out. The clearest kind of opt-out would entail purging of information from the PPCC database. An alternative, that would be less effective from a privacy standpoint, would be to require the masking of the identity of a woman who chooses to opt-out. That would give rise to questions about whether, or how, the personal health information could be re-identified.

I recognize that there is a concern that much of the value of a screening program may be lost if it fails to capture the data on all eligible women in the province. On the other hand, the experts that developed the PPCC were originally prepared to provide for an opt-out. Such a feature is consistent with national standards for population cancer screening.[4] This feature was eliminated at about the time it became clear HIPA would be amended in 2003 to remove any consent requirement for the relevant transactions. Manitoba presumably is attempting to meet the same kind of national standard as this province and yet does offer an opt-out. New Zealand has explored different kinds of arrangements for women who did not wish to be part of the cervical cancer screening program in that nation and has now settled on a full opt-out. The experience in those jurisdictions suggests that, since a small number of women exercise the right to opt-out, the value of the cervical cancer screening program has not been unduly prejudiced.

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[4] *Population Cancer Screening in Canada: Strategic Priorities*. Cancer Strategy for Cancer Control: Screening Working Group Final Report, January 2002, Page 10.

II EXECUTIVE SUMMARY (CONT'D)

C. The need for an opt-out mechanism for Saskatchewan women (cont'd)

The opt-out I contemplate would not prevent either of the two major health regions from utilizing the Saskatchewan Cancer Agency for purposes of information management services provided that that personal health information is not available to the Agency for purposes of the PPCC.

It was suggested at one time by Agency representatives that the PPCC was a tool to empower women by ensuring they had more information about their cervical health. I agree that as a general rule more information can be a way of empowering the individual. In this privacy context however, the collection of personal health information at the front end of the process is critical since all other activities flow from the point of collection. At the point of collection for the PPCC, a Saskatchewan woman is effectively powerless.

This has been the first significant opportunity for our office to examine the key provisions of HIPA in the context of an operating health program. From a privacy standpoint, I am concerned at the sweep of the no-consent rule in section 27(2)(b). I am also concerned that there is no requirement that the wishes of the patient must be considered by a trustee in collecting, using or disclosing that information without consent. There is no right to find out after the fact about disclosures made by a trustee of personal health information if section 27(2)(b) applies. That provision represents a very substantial departure from the common-law concept of patient autonomy that would have applied in Saskatchewan prior to September 1, 2003.

II EXECUTIVE SUMMARY (CONT'D)

I note that this Saskatchewan approach appears to be at odds with the federal *Personal Information Protection and Electronic Documents Act*[5] that applies to Saskatchewan physicians and pharmacists when they are engaged in commercial activities. The Saskatchewan approach also appears to be at odds with the *Pan-Canadian Health Information Privacy and Confidentiality Framework* developed by Canadian provinces, territories and the federal government. Perhaps more importantly, section 27(2)(b) of HIPA appears to be at odds with the right of privacy that the Supreme Court of Canada has declared is protected by the *Canadian Charter of Rights and Freedoms*.[6]

I considered whether there is a way to interpret section 27(2) in a way that is consistent with our understanding of the Charter. To that end, I have carefully reviewed the legislative history of HIPA and *Hansard* debates when the bill was being considered by legislators.

My conclusion is that the Legislative Assembly very deliberately intended to limit the role of consent in the manner apparent in section 27(2)(b). I have not found an appropriate way that I can interpret section 27(2) to limit its sweep without ignoring the very clear direction from the Legislative Assembly.

Nonetheless, I recommend that the Legislative Assembly revisit the consent requirement in HIPA and particularly consider the value of incorporating an implied consent feature. This would allow a trustee to infer consent when personal health information is collected, used or disclosed for appropriate health care purposes but would also accommodate a patient opt-out. Alternatively, I recommend that the Saskatchewan government consider seeking direction from the Saskatchewan Court of Appeal as to whether the apparent conflict between section 27(2) in HIPA and the Charter is a real conflict.

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5 *Personal Information Protection and Electronic Documents Act*, S.C. 2000, c.5 [hereinafter "PIPEDA"]

6 *Canadian Charter of Rights and Freedoms*, Part I of the Constitution Act 1982, being Schedule B to the Canada Act 1982 (U.K.), 1982, c.11 [hereinafter "The Charter"]

III FINDINGS

(1) I find that a Saskatchewan woman would have a reasonable expectation of privacy in respect of her cervical health information.

(2) I find that when the personal health information is particularly sensitive such as cervical health information, the threshold for transparency should be a higher standard.

(3) I find that a trustee cannot rely on the provisions in HIPA for collection, use and disclosure of personal health information without express or implied consent in sections 26, 27 and 28 unless that trustee has first satisfied the general duties in sections 9, 10, 16, 19, 23.

(4) I find that the Agency has the primary responsibility for communicating information about the PPCC to Saskatchewan women.

(5) I find that the Saskatchewan Cancer Agency has failed to discharge its duty under section 9 of HIPA in that it has failed to ensure all Saskatchewan women are informed about the anticipated uses and disclosures of their cervical health information for purposes of the PPCC.

(6) I find that to discharge its obligation under section 16 of HIPA, a trustee must address three different kinds of safeguards: (1) administrative; (2) technical and (3) physical.

(7) I find that the Agency has appropriate technical and physical safeguards as required by section 16 of HIPA except for the need to take further steps to minimize the risk of access by an unauthorized person to Pap test results when they are transmitted by the Agency.

(8) I find the Agency has met the requirements for administrative safeguards contemplated by section 16 of HIPA except for the need to create an access form separate from a consent to disclosure form.

(9) I find that the Agency has satisfied the requirements of section 23(2) of HIPA.

III FINDINGS (CONT'D)

(10) I find that a significant number of family physicians in Saskatchewan have not provided their female patients with sufficient information about the PPCC and how it operates.

(11) I find that the collection of personal health information by the Agency conforms with sections 23(1), 24(1) and 25(1)(f) of HIPA.

(12) I find that the use of personal health information by the Agency conforms with section 26(2)(a) of HIPA.

(13) I find that the disclosure of personal health information, namely registration information from the Person Registry System, by Saskatchewan Health to the Agency conforms with section 28(1)(a) of HIPA.

(14) I find that the disclosure of personal health information, namely vital statistics information, from Saskatchewan Health to the Agency conforms with section 29(2)(h)(v) of *The Freedom of Information and Protection of Privacy Act*.[7]

(15) I find that the disclosure of personal health information to the Agency from the RQRHA and the SRHA conforms with section 27(2)(a), 27(2)(b) and 27(4)(j) of HIPA.

(16) I find that the Agency is an "information management services provider" within the meaning of section 2(j) of HIPA insofar as it deals with 12 of the 59 data elements which are not necessary for purposes of the PPCC.

(17) I find that the Agency is not an "information management services provider" within the meaning of section 2(j) of HIPA insofar as it deals with the remaining 47 data elements disclosed by the regions to the agency for purposes of the PPCC.

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[7] *The Freedom of Information and Protection of Privacy Act*, S.S. 1990-91, c. F-22.01 [hereinafter "FOIP"]

III FINDINGS (CONT'D)

(18) I find that the disclosure of personal health information related to the PPCC by the Agency to regional health authorities conforms with section 27(2) of HIPA.

(19) I find that in so far as the PPCC is concerned, the RQRHA and SRHA have established policies and procedures as required by section 27(3)(a).

IV RECOMMENDATIONS

A. For the Saskatchewan Cancer Agency

(1) That the Agency incorporate an 'opt-out' feature in the PPCC that will allow any Saskatchewan woman to opt-out of the PPCC and have her identifiable information purged from the PPCC database. This opt-out should be clear, simple and be communicated to all Saskatchewan women and to all Saskatchewan family physicians. This should include information on the consequences of opting out of the PPCC.

(2) That the Agency consult with its partners, RQRHA and SRHA, to determine what changes will be necessary to the contractual arrangements between these organizations to permit any Saskatchewan woman the right to withdraw, or opt-out, of the PPCC.

(3) That the opt-out should not prevent either RQRHA or SRHA from making arrangements to store and manage this data provided that data remains under the control of the regions and is not further disclosed.

(4) That the Agency review its organizational structure to ensure that the Privacy Officer will have a clear and direct reporting arrangement with the CEO of the Agency.

IV RECOMMENDATIONS (CONT'D)

A. For the Saskatchewan Cancer Agency (cont'd)

(5) That the Agency consider a dual appointment such that the Privacy Officer is also the Access and Privacy Coordinator for purposes of *The Local Authority Freedom of Information and Protection of Privacy Act*[8].

(6) That the Agency consider a revision of the job description for the Privacy Officer to include liaison with the Office of the Saskatchewan Information and Privacy Commissioner for purposes of HIPA compliance.

(7) That the Agency consider a requirement that in addition to what has already been done, all Agency staff receive basic HIPA awareness training including information on privacy so that staff not only know the rules, but have a comfortable understanding of the larger privacy context.

(8) That the Agency develop printed materials to utilize for training of new and current employees to ensure that employee performance can be evaluated against clear standards and requirements.

(9) That the Agency revise its printed material and website content that will clarify for Saskatchewan women and physicians the following items:

- The legal authority for the PPCC.
- The legal authority for the collection, use and disclosure of cervical health information without consent.
- An opt-out procedure.
- Security standard.
- Other disclosures of the information.
- PPCC linkage with family physicians.
- Reference to the oversight provided by the Office of the Information and Privacy Commissioner and contact information for the OIPC.

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[8] *The Local Authority Freedom of Information and Protection of Privacy Act*, S.S. 1990-91, L-27.1, (available on-line: http://www.qp.gov.sk.ca/documents/English/Statutes/Statutes/L27-1.pdf) [hereinafter called "LAFOIP"]

IV RECOMMENDATIONS (CONT'D)

A. For the Saskatchewan Cancer Agency (cont'd)

(10) That the Agency task someone with specific responsibility to routinely survey access activities in respect to electronic personal health information to ensure there is no unauthorized or inappropriate access.

(11) That the Agency continue its practice of not data matching cervical cancer and breast cancer screening information. In the event that at some future time it wishes to data match, it should either have consent or first complete a Privacy Impact Assessment and provide that to the Office of the Saskatchewan Information and Privacy Commissioner for review and comments.

(12) That the Agency undertake a Privacy Impact Assessment prior to creating any new program that will impact the privacy of Saskatchewan women, or the confidentiality of their information, or any new information management services project, and provide that to the Office of the Saskatchewan Information and Privacy Commissioner for review and comments.

(13) That the Agency revise its form for access to information by an individual woman to:

- Reflect the clear difference between a right of access provided by section 32 of HIPA and the discretionary disclosure provided for by section 27; and
- Reflect the provisions for a surrogate to make such an access request pursuant to section 56 of HIPA.

(14) That the Agency provide contact information on its website for its Privacy Officer and provide information for a woman who wishes either to complain or to seek further information about the PPCC. This should include information about the right to seek a review by the Office of the Saskatchewan Information and Privacy Commissioner.

IV RECOMMENDATIONS (CONT'D)

A. For the Saskatchewan Cancer Agency (cont'd)

(15) That the Agency take further steps with the College of Physicians and Surgeons and the Saskatchewan Medical Association to ensure that all Saskatchewan women have access to complete and accurate information about the PPCC, particularly at the first time a woman provides a Pap specimen. This effort should ensure that all Saskatchewan physicians are equipped to advise their female patients about the PPCC.

(16) That the Agency consider how best it can inform all Saskatchewan women of their right to access personal health information in the custody or under the control of the Agency and to seek a correction when appropriate.

B. For Saskatchewan Health

(1) That Saskatchewan Health make information available for women on their rights and obligations under HIPA. This should include information with respect to the circumstances where their personal health information can be collected, used and disclosed without their express or implied consent and without their knowledge. This should involve both information on the Department website and printed materials.

(2) That Saskatchewan Health consider the development of some form of Help Desk that can be accessed by trustees and citizens seeking information concerning HIPA. Such a resource should be widely advertised within the province.

(3) That Saskatchewan Health take the appropriate steps to ensure the Saskatchewan Cancer Agency is clearly identified in its enabling legislation.

(4) That Saskatchewan Health consider amending HIPA to ensure that quality assurance projects undertaken by a trustee, as a use, should be subject to a process analogous to that of a research ethics committee under section 29.

IV RECOMMENDATIONS (CONT'D)

B. For Saskatchewan Health (cont'd)

(5) That Saskatchewan Health consider amendment of section 27(2) of HIPA to substitute "implied consent" for "deemed consent" to reflect recent Canadian developments in health information regulation.

(6) That, in the event there is no amendment of section 27(2), Saskatchewan Health consider a requirement in HIPA that a trustee must consider the express wishes of an individual in determining how much personal information should be disclosed.

(7) That Saskatchewan Health consider a reference by the Lieutenant Governor in Council to the Court of Appeal to determine whether the apparent conflict between section 27(2) in HIPA and the *Charter of Rights and Freedoms* is a real conflict.

C. For Saskatchewan Physicians

(1) That Saskatchewan family physicians should inform their female patients about the PPCC the first time a Pap specimen is taken and alert them that they will be receiving notification directly from the Agency in the future.

(2) The College of Physicians and Surgeons should take appropriate steps to ensure that there is informational material available to all Saskatchewan women who attend at their physicians' office for a Pap test. This material should explain the PPCC and in particular the direct contact with women that is a feature of the PPCC.

V AUTHORITY

The legal authority for our investigation of the PPCC is found in sections 42, 52 and 53 of *The Health Information Protection Act* (HIPA):

"42(1) A person may apply to the Commissioner for a review of the matter where:

. . .

(c) the person believes that there has been a contravention of this Act.

52 The commissioner may:

(a) offer comment on the implications for personal health information of proposed legislative schemes or programs of trustees;

(b) after hearing a trustee, recommend that the trustee:

(i) cease or modify a specified practice of collecting, using or disclosing information that contravenes this Act; and

(ii) destroy collections of personal health information collected in contravention of this Act;

(c) in appropriate circumstances, comment on the collection of personal health information in a manner other than directly from the individual to whom it relates;

(d) from time to time, carry out investigations with respect to personal health information in the custody or control of trustees to ensure compliance with this Act;

(e) *comment on the implications for protection of personal health information of any aspect of the collection, storage, use or transfer of personal health information.*

53 The commissioner may:

(a) engage in or commission research into matters affecting the carrying out of the purposes of this Act;

(b) conduct public education programs and provide information concerning this Act and the commissioner's role and activities;

(c) receive representations concerning the operation of this Act."

VI INVESTIGATION PROCESS

This file was opened after our office saw news reports in December, 2003 concerning the PPCC. We contacted the Agency to advise that we wanted to learn more about the PPCC and to consider the program through a HIPA filter. We had an early meeting with the Chairman of the Agency and the Executive Director of Prevention and Early Detection in January, 2004, and agreed on a process that would involve certain internal materials being assembled and delivered to our office.

Initially, we expected this would be a relatively simple review of a single health program. It became more and more complex as we came to learn more about the scope and range of the PPCC and the interlinkages with many other health information trustees.

We had a number of meetings with officials of the Saskatchewan Cancer Agency. It became clear that it would be useful for our office to produce a detailed report that would attempt to review the purpose and operation of the PPCC, interpret the applicable legislation, and offer advice and recommendations for changes as warranted.

This included a very helpful onsite review of those operations of the Agency in its Regina offices relevant to the PPCC and the security features of the Agency.

I undertook a site visit to the Saskatoon Regional Health Authority laboratory facility in the Saskatoon City Hospital. I was impressed with the professionalism and commitment to privacy and confidentiality evident among the staff of that facility.

We have had discussions with officials of the Saskatchewan College of Physicians and Surgeons since physicians play a key role as primary health care providers to Saskatchewan women who are involved with the screening program.

VI INVESTIGATION PROCESS (CONT'D)

We have obtained considerable information and materials from Saskatchewan Health which has been very helpful in understanding the role played by that department in the PPCC including what kind of information it shares with the Agency and why.

Starting in January of 2004, we began to receive complaints from Saskatchewan women by letter, fax, email and phone concerning the PPCC. We talked to many of these women and discovered that a number of them had invested considerable time and effort in documenting concerns and reporting on the kind of response they had received from different trustees. A number of these women had encouraged our office to hold one or more "town-hall" meetings to allow a public discussion of the issues. Our decision was that we would better serve our statutory mandate by focusing our efforts on completing a thorough review of the screening program and making our report publicly available.

We have gathered information from cancer screening programs in New Zealand and in other Canadian jurisdictions. We have benefited from the generous advice provided by the New Zealand Privacy Commissioner. We also have canvassed researchers and health information experts in Saskatchewan and outside the province in our investigation.

I wish to acknowledge the full cooperation we received in our dealings with the Agency and its representatives. The Agency has requested that we provide what advice we think appropriate to ensure full compliance with both applicable legislation and privacy best practices. This openness on the part of the Agency is a testament to the professionalism of the organization.

VI INVESTIGATION PROCESS (CONT'D)

We have constructed a complex health care delivery system in this province that encompasses a wide variety of public sector and private sector care providers collecting, using and disclosing a great deal of personal health information. This entails a staggering number of different transactions and substantial complexity. One of the foundations of that health care system is patients who are comfortable in disclosing fully and frankly their symptoms and health history to the appropriate health care provider. If Saskatchewan women are anxious over what happens with their personal health information the risk is that this kind of frank sharing of personal health information may be jeopardized.

This review has taken an unacceptable length of time to complete. I apologize to the women who asked our office to investigate this matter and to the trustees who have been patiently awaiting this report. This was the first investigation under HIPA our fledgling office undertook since our full-time office was opened in November, 2003. When we initially undertook the review, our office consisted of only the Commissioner and the Office Manager. It was only after the Assistant to the Commissioner was hired in late March, 2004, that we were able to commit substantial time to this investigation. Our early estimate of time to complete this review was 40 or 50 hours. In fact, we have spent many hundreds of hours in this investigation. It is clear that our office simply does not have the capacity to undertake such a major project and complete it within a reasonable time frame. This experience is now reflected in our Business Plan for 2005-2008 and specifically Goal 4 that is identified and discussed on page 15. Our plan is to strengthen our investigatory capacity. The Business Plan is accessible at our website: www.oipc.sk.ca.

I want to specifically acknowledge the magnificent contribution to this project by my assistant, Diane Aldridge. Her diligence, resourcefulness and research skill have been indispensable to completion of this project.

VII KEY TERMS

Histology -- the microscopic examination of the structure and composition of cells and tissues by a pathologist.[9]

Cervix -- A narrowed part of the uterus extending into the vagina[10].

Cytology -- The microscopic study of cells that have been shed or scraped from the cervix, uterus, lungs, bladder, or skin to check for cancer. An example of this procedure is the Pap test, used to detect cervical cancer[11].

Colposcopy -- A procedure in which the vagina and cervix are visually examined through an instrument with an attached magnifying lens.[12]

Pap test -- Microscopic examination of cells scraped from the cervix. Devised by Dr. George Papanicolaou, the Pap test is an effective way to detect both cervical cancer and pre-cancerous changes to the cervix.[13]

Screening -- Testing for disease in healthy people with no symptoms. Not all diseases can be screened. The decision to screen healthy people for a disease depends on many factors including the availability of a test, the nature of the disease, the characteristics of the population and the ability of the healthcare system to cope with follow-up, diagnosis, and treatment.[14]

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9 *The Canadian Cancer Society Encyclopaedia.* The Canadian Cancer Society, 2004. (available online at http://www.bc.cancer.ca/ccs/internet/standard/0,3282,3278_10127_langIden.00.html) [hereinafter called "The Encyclopaedia"]

10 Ibid.

11 Ibid.

12 Ibid.

13 Ibid.

14 Ibid.

VII KEY TERMS (CONT'D)

Trustee -- This includes all of the provincial government departments, Crown Corporations, boards, agencies and commissions listed as a "government institution" in *The Freedom of Information and Protection of Privacy Regulation*; regional health authorities; the Saskatchewan Cancer Foundation; a health professional body such as the College of Physicians and Surgeons; and health professionals, such as family physicians, licensed to practice in the province and other organizations specified in HIPA.[15]

Privacy -- The right of an individual to control the collection, use and disclosure of personal health information about himself or herself[16]

Use -- Use includes reference to or manipulation of personal health information by the trustee that has custody or control of that information but does not include disclosure to another person or trustee[17]

Disclosure – refers to the release, transmittal, exposure, revealing, showing, providing copies of, telling the contents of, or giving health information by any means to any person or organization. It includes disclosure to another trustee, custodian or to a non-trustee.[18]

Secondary Purpose -- Personal health information that is used or disclosed for a purpose other than the diagnosis, treatment or care of a particular patient

Security -- The protection of personal health information from unauthorized or unintentional loss, theft, access, use, modification, or disclosure[19].

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15 HIPA, supra, note 1, section 2(t)

16 *Privacy and Confidentiality of Health Information at CIHI: Principles and Policies for the Protection of Personal Health Information and Policies for Institution-Identifiable Information*, 3rd Edition, Ottawa: Canadian Institute for Health Information, April 2002, Page 52 [hereinafter "Privacy and Confidentiality"]

17 HIPA, supra, note 1, section 2(u)

18 *The Health Information Act: Guidelines and Practices Manual*. Edmonton: Information Services Unit, Alberta Health and Wellness, 2001, Page 192

19 Privacy and Confidentiality, supra, note 16, page 53

VIII CANCER REGISTRY OR CANCER SCREENING

It is important to distinguish between a cancer registry and a cancer screening program. Although both may be a type of "health surveillance" there are some important differences.

A cancer registry maintains data on women and men who have been diagnosed with any type of cancer. Legislation makes participation in the registry compulsory. In Saskatchewan, the cancer registry is mandated by *The Cancer Foundation Act*.[20] This has been a traditional activity of cancer agencies across Canada for many years. In Saskatchewan, the Agency has functioned as a provincial body to collect and integrate personal health information about the incidence, treatment and outcomes of cancer. That registry represents a kind of platform on which the Agency's services and research have been based. When British Columbia's first Information and Privacy Commissioner investigated the British Columbia Cancer Agency, he was examining the cancer registry. He found a number of deficiencies and offered 29 recommendations.[21] We have not reviewed Saskatchewan's cancer registry in this investigation and have restricted our focus to the PPCC.

In contrast to the cancer registry, a cancer screening program maintains data on the target population, the vast majority of whom do not have cervical cancer. In the case of cervical cancer, the target population is approximately 300,000 Saskatchewan women between 18 and 69 years of age. All Saskatchewan women in that age range, except for those who have had a hysterectomy, are automatically enrolled in the PPCC. The purpose of screening is to identify women at risk of developing cervical cancer and then taking active steps to encourage these women to undergo regular Pap testing.

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[20] *The Cancer Foundation Act*, S.S. 1979, c-2.1. (Section 16 requires a physician or dentist who examines, diagnoses or treats a patient to furnish to the foundation any information requested.) (available on-line: www.qp.gov.sk.ca/documents/English/Statutes/Statutes/C2-1.pdf)

[21] The British Columbia Cancer Agency: *The Results of a Privacy Check-Up*. Presented to North American Association of Central Cancer Registries, Boston, MA, April 1, 1997. (available online at www.oipc.bc.ca)

IX PRIVACY EXPERIENCE WITH CANCER REGISTRIES

Although we have not reviewed the cancer registry in Saskatchewan, there may be some experience with cancer registries that is relevant in assessing the screening programs in general and the Saskatchewan PPCC in particular. Both the cancer registry and the PPCC are surveillance programs.

I have found that a useful resource is a document entitled *Use of Cancer Patient Information for Surveillance Purposes -- A Systematic Review of Legislation, Regulations, Policies and Guidelines.*[22] I note that in that document "surveillance" has been defined in different ways:

> *"1. Systematic measurement of health and environment parameters, recording, and transmission of data."*
>
> *2. Comparison and interpretation of data in order to detect possible changes in the health and environmental status of populations.*
>
> *3. Tracking and forecasting any health event or health determinant through the ongoing collection of data, the integration, analysis and interpretation of that data into surveillance products and the dissemination of that resultant surveillance product to those who need to know. Surveillance products are produced for a predetermined public health purpose or policy objective.*
>
> *The essential characteristics of surveillance are the ongoing or systematic collection, analysis and dissemination of data. Various types of surveillance have been distinguished, for example "active surveillance," in which data are obtained by a proactive search and contact with health care providers, in contrast to "passive surveillance," in which the recipient of the data initiates or establishes a system but then waits for health care providers to report, possibly pursuant to a legal or other duty to provide information*

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[22] Tigerstrom, B.von, Mylene Deschenes, Bartha Maria Knoppers and Timothy A. Caulfield. *Use of Cancer Patient Information for Surveillance Purposes: A systematic Review of Legislation, Regulations, Policies, and Guidelines.* The Canadian Coalition on Cancer Surveillance, March 2000 (available online: www.law.ualberta.ca/centres/hli/pdfs/hlr/v8/cancerfrm2.pdf) [hereinafter "Use of Cancer "]

IX PRIVACY EXPERIENCE WITH CANCER REGISTRIES (CONT'D)

These types of systems may be used in combination. Furthermore, a combination of the various possible types of information may be used. Common sources include the following:

1. *Notifiable disease and related reporting systems;*
2. *Vital statistics;*
3. *Sentinel surveillance (using a selected sample to monitor key health indicators in the general population);*
4. *Registries;*
5. *Surveys; and*
6. *Administrative data-collection systems.*

Registries differ from other sources in that they link data from multiple sources into consolidated information for each individual. This linking allows each new case to be identified but not counted more than once. The use and importance of registries have increased in recent years."[23]

The authors make some interesting observations on the impact of privacy protection:

"The questions at the forefront of cancer registration these days are related to issues of privacy and confidentiality. With the rise of privacy protection, particularly in Europe, cancer registration along with any other type of epidemiological studies or morbidity surveillance have difficulty in finding a way to proceed without contravening the established legislation. There is a tension between the need to have a thorough review of all cancer incidence in a given territory and the need to respect increasingly severe rules of confidentiality. Often the rules on confidentiality provide that consent is required before data are gathered on a person. We even see opt-out provisions. Such a procedure is not appropriate or compatible with cancer registration. For cancer surveillance to be efficient, it must be done on the population at large."[24]

I note that the above noted comments appear to relate to the more traditional kind of cancer registry since Canadian experience with screening programs has been relatively limited.

[23] Ibid., page 4 and 5
[24] Ibid, page 64

IX PRIVACY EXPERIENCE WITH CANCER REGISTRIES (CONT'D)

I also note that the International Agency for Research on Cancer published *Guidelines on Confidentiality in Population-Based Cancer Registration in the European Union*. The authors observe as follows:

> *"The informed consent principle makes it virtually impossible to use data from a cancer registry, for various reasons:*
>
> *(a) The practical workload of seeking consent each time data are processed is a disproportionate and very heavy burden for population-based cancer registries.*
>
> *(b) The repeated burden to the patients and/or their relatives being asked to consent is of concern.*
>
> *(c) Seeking general consent for whatever scientific and statistical use of the cancer registration process poses a further load on medical personnel and may lead to unacceptably low coverage of registration (as seen in Hamburg).*
>
> *(d) From a legal point of view, consent can only be given for a limited period of time.*
>
> *(e) The proportion of non-coverage (resulting from differences in patterns of asking for or giving consent) may vary by population, and true differences in cancer incidence may become confounded by differences in the accuracy of the registration."*[25]

Clearly that report and its conclusions relates to a cancer registry. This is defined in that report as *"an organisation for the collection, storage, analysis and interpretation of data on persons with cancer."* [26][emphasis added]

In another report, the following comments appear:

> *"As a general rule, obtaining the subject's consent is the way that one legitimizes what would otherwise be a breach of confidentiality and the right to privacy. In surveillance and some health research, however, a consent requirement is problematic because it precludes comprehensive coverage. These considerations may justify collection, use and disclosure of information without informed consent, although only to the extent that is truly necessary. The justification for dispensing with consent may not extend beyond basic surveillance activities and research; further discussion and public debate of the exact scope of this justification is required.*

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[25] *Guidelines in Population-based Cancer Registration in the European Union*. European Network of Cancer Registries, February 2002, page 4 [hereinafter "Guidelines in the European Union"]

[26] Ibid, page 5

IX PRIVACY EXPERIENCE WITH CANCER REGISTRIES (CONT'D)

However, we also need to consider the principle of transparency, which is a related but distinct principle from informed consent. Transparency requires that individuals and the public at large be aware of surveillance activities and the information practices of cancer agencies. This principle of transparency should be adhered to even when consent is not required. Public education on the activities of cancer registries and the benefits of cancer registration should also help to establish support for these activities."[27]

X THE PREVENTION PROGRAM FOR CERVICAL CANCER
(Background Information)

A. The Agency's Mandate

The PPCC is a program of the Agency.

The Saskatchewan Cancer Agency, is a public body created pursuant to *The Cancer Foundation Act*. The SCA is responsible for the provision of cancer treatment, prevention and early detection programs, research, and education services to the people of Saskatchewan. The Agency operates the Allan Blair Cancer Center in Regina, Saskatoon Cancer Centre, two cancer patient lodges, a health division, the Screening Program for Breast Cancer (SPBC), and the Prevention Program for Cervical Cancer (PPCC). This review considers only the cervical cancer screening program of the Agency.

[27] Use of Cancer, supra, note 22, page 78

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

The "Saskatchewan Cancer Agency" is the operating name of the Saskatchewan Cancer Foundation. The Foundation is a body corporate established pursuant to section 5 of *The Cancer Foundation Act*. The Agency is the successor to the Saskatchewan Cancer Commission which previously operated under *The Cancer Control Act*. *The Cancer Control Act* was repealed when *The Cancer Foundation Act* came into force. The regulations under *The Cancer Control Act* continue in effect, except to the extent they are inconsistent with the main body of *The Cancer Foundation Act*.

Section 11 of *The Cancer Foundation Act* states as follows:

"11 The foundation shall conduct a program for the diagnosis, prevention and treatment of cancer which shall include:

(a) the laboratory and clinical investigation of cancer problems;

(b) the co-ordination of facilities for treatment of cancer;

(c) the continued operation of clinics operated under The Cancer Control Act and the establishment and operation of any clinics that the foundation may consider advisable for the examination and diagnosis or treatment of patients in the province or persons suspected of being afflicted with cancer or with any other disease or condition which any clinic may become equipped to examine, diagnose or treat;

(d) the establishment, maintenance and operation of hostels in connection with clinics or participation with any other person in the establishment, maintenance and operation of those hostels;

(e) the adequate reporting of cases of cancer and the recording and compilation of data relating to cancer;

(f) the education of the public in the importance of early diagnosis, prevention and treatment of cancer;

(g) the provision of facilities for undergraduate and post-graduate study relating to cancer;

(h) the training of technical personnel to assist in the examination, diagnosis, treatment or study of cancer;

(i) the provision of funds to physicians and other qualified persons for post-graduate training concerned with cancer;

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

(j) the adoption of any measures that may be considered necessary for preventing or minimizing the development or spread of cancer;

(k) the correlation and co-ordination, by voluntary means, of the work and studies of all agencies, clinics or persons in the province that may have similar objects or purposes or that may be carrying on similar or related work or studies;

(l) the study of radiation hazards arising from the use of x-ray generators and radioactive materials and substances and recommendations for the establishment of protective devices and facilities in respect of those hazards;

(m) the conduct of, the participation in or the provision of assistance for research projects in connection with the diagnosis, prevention or treatment of cancer."

B. Cervical Cancer

Cervical cancer is an invasive cancer that develops when abnormal cells of the cervix are not treated. There are no signs or symptoms of cervical cancer in its early stages. Cytopathology is the practice of medicine specializing in diagnosis through the evaluation of the cellular manifestations of disease and consulting in the decision-making related to the patient's subsequent management.[28] Cytology is a diagnostic procedure based upon the study of cells using a microscope. An example of this procedure is the Pap smear, used to detect cells that may lead to cervical cancer. Colposcopy is, *"a microscopic examination of the cervix performed for the diagnosis of cervical abnormalities"* or *"a procedure in which the vagina and cervix are visually examined through an instrument with an attached magnifying lens."*[29]

The Pap test result is the best way of detecting cancer early before it becomes symptomatic. During a pelvic examination, the health care provider performs a Pap test by scraping cells from a women's cervix and placing the cells on a microscope slide. At the laboratory, the slide is analysed for abnormal changes in the cells. Changes may indicate a pre-cancerous condition, which with easy treatment may prevent the cancer from developing.[30]

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28 *Canadian Society of Cytology Guidelines for Practice and Quality Assurance in Cytopathology*. Quality Control Committee of the Canadian Society of Cytology, September 1996, page 3.

29 The Encyclopaedia, supra, note 9

30 Pamphlet: *Cervical Screening in Your Hands, Prevention Program for Cervical Cancer, A Program of the Saskatchewan Cancer Agency* [hereinafter "Cervical Screening"]

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

B. Cervical Cancer (cont'd)

A Pap test will have one of three primary results: normal, unsatisfactory, or abnormal. An unsatisfactory indicates that the Pap test could not be read at the laboratory and, the test may need to be repeated. Abnormal indicates that a change in the cells of the cervix has been detected. This is not necessarily cause for concern, as the majority of abnormal results are minor changes, or simple conditions easily treated. If never or infrequently tested, or without necessary follow-up and treatment, approximately 15-20 women die from cervical cancer in Saskatchewan each year.[31]

This statistic is further supported in the *Final Report: The Task Force for Cervical Cancer Screening – A Screening Program for Cervical Cancer*, October 1999:

> *"In 1997, the Health Services Utilization and Research Commission completed a study, which indicated that approximately 21% of Saskatchewan women have never been tested for cervical cancer and another 20% were tested infrequently. The major proportion of under-screened women fall into one or more of the following: low income; reside in rural or remote areas; are of minority ancestry (e.g., first nations, new immigrants, etc). The study also identifies that approximately 20% of women are screened more frequently than national guidelines indicate necessary."*[32]

The purpose of screening is to detect cancers early, even though no symptoms may be present. Early detection of cancer, in this case cervical cancer, through screening allows doctors to treat cancer in the early stages when a person has a greater chance of recovery. Screening is:

> *"the presumptive identification of unrecognized disease...by the application of tests, examinations, or other procedures which can be applied rapidly to sort out apparently well persons who probably have a disease from those who probably do not (Commission on Chronic Illness, 1957).*
>
> *The objective of screening is:*
>
> *the early detection of pre-symptomatic disease in order to permit treatment which is more effective or easier to apply at that stage."*[33]

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31 Ibid

32 Final Report, supra, note 2, page 12

33 Pamphlet: Cervical Screening, *The Program. Prevention Program for Cervical Cancer, A Program of the Saskatchewan Cancer Agency* [hereinafter "The Program"]

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

B. Cervical Cancer (cont'd)

Since the 1970s, opportunistic screening for cervical cancer has occurred in Saskatchewan. This type of screening has played a significant role in reducing the incidence of and mortality rates associated with cervical cancer. Further reductions of incidence and mortality may result if screening becomes more organized and systematic.[34]

> *"Approximately 90% of deaths from cervical cancer can be eliminated by population screening with the Papanicolaou (Pap) test and appropriate follow-up. Screening coverage in Saskatchewan is currently incomplete, however, and at least one fifth of women in the province are not tested regularly*
>
> *The 1989 National Workshop on Screening for Cancer of the Cervix recommended an organized approach to screening be established in each province to ensure all women are adequately tested and receive appropriate follow-up. A comprehensive program in Saskatchewan requires implementation of an information system with registry and recall functions, targeted recruitment, quality assurance in the laboratory and clinic, public and professional education, ongoing surveillance, and education."*[35]

One report[36] explains the need for cervical cancer screening programs including the following:

- *"Cancer of the cervix is a potentially preventable disease, yet a significant number of cases occur in Canada each year;*
- *It is economically sound to prevent the disease;*
- *Since the 1970's, there have been a decrease in the rate of decline of invasive cancer of the cervix in women under 50 in Canada, in contrast to an increase in in-situ disease, a pre-invasive condition;*
- *Opportunistic screening does not achieve optimal screening coverage and appears to have reached the limits of its effectiveness;*
- *Women who are diagnosed with the disease are those who have not been screened;*
- *Organized programs have been shown to be effective;*
- *The costs of organized programs are probably less than that of opportunistic screening; and*
- *Organized programs allow for the evaluation and monitoring of screening and follow up activities."* (page 6)

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[34] Final Report, supra, note 2, page 8

[35] Health Services Utilization and Research Commission. *A Comprehensive Approach to Cervical Cancer Screening*. Summary Report No. 8, January 1997, page 1 [hereinafter "HSURC"]

[36] *Programmatic Guidelines for Screening for Cancer of the Cervix in Canada*. Quality Management Working Group Cervical Cancer Prevention Network, Health Canada, 1998 (available on-line: www.hc-sc.gc.ca/hppb/ahi/cervicalcancer/pubs/screening.pdf) [hereinafter "Programmatic Guidelines"]

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

B. Cervical Cancer (cont'd)

The rationale in a 1999 Report[37] echoes those reasons offered above, but also include the following: possibly saving lives through appropriate screening, follow-up and treatment of the target groups; saving money as a result of reduced cancer treatment costs, through the reduction of unnecessary tests and lab costs, reducing follow-up costs for low-grade abnormalities; ability to track providers to identify who requires additional training; utilizing new technology to improve false negative call rates; allowing for improvements to the current information systems improving access to, processing of, quality and integrity of the data. A necessary component of a cervical cancer screening program is *"research and evaluation, which ensures evolving practice techniques are reviewed in the context of health system and population based outcomes"*.[38]

A more recent rationale for the program is provided in a pamphlet created by PPCC: Cancer of the cervix is preventable, yet many cases still occur; cancer is less costly to prevent than to treat; the majority of women diagnosed with cervical cancer are infrequently or never tested for pre-cancerous conditions; organized screening programs are effective in preventing cervical cancer through tracking individual participation, education and notification initiatives; individualized notification and recall are the most effective methods of recruiting hard to reach populations; and organized programs allow for the evaluation and monitoring of screening and follow-up activities.[39]

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[37] Final Report, supra, note 2, pages 12-14
[38] Ibid, page 5
[39] The Program, supra, note 33

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

B. Cervical Cancer (cont'd)

The Agency asserts that in order for a population-based screening program to be successful, all components, as outlined in the 1989 National Workshop on Screening for Cancer of the Cervix, and recommended by the Health Services Utilization and Research Commission (HSURC) need to be in place.

Those components would include: a comprehensive database to allow other components to be implemented; education of the targeted population; high participation in screening among the target population; quality assurance/quality improvement at all stages of the screening process; a process that ensures women with non-normal results receive diagnosis and if needed, treatment; and ongoing monitoring and evaluation of program effectiveness.[40]

The 1997 Report lists key findings, barriers, solutions and recommendations. One key solution identified to resolve barriers to screening focuses on the nature of the physician-patient relationship. *"Women like to be reminded by their physicians that it is time for their test"*[41]. The recommendations of this Report do not address this issue directly. The primary recommendation was for the Saskatchewan Cancer Foundation (SCF) to develop an organized cervical cancer screening program.

> *"The Saskatchewan Cancer Foundation was identified as the ideal "host" for a cervical cancer screening program for a number of reasons: it is a provincial public body with expertise in the area of cancer screening; it could address cervical cancer screening with a holistic "well-woman" framework by linking aspects of cervical and breast health; and, it would be able to develop and maintain the registry and recall functions in conjunction with its existing information system. Such a program would also be publicly accountable"*[42].

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40 Package received with letter September 24, 2004 from the Agency, pages 1-2 [hereinafter "The Package"]
41 HSURC, supra, note 35, page 4
42 Ibid, page 7

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

C. Preparations for the PPCC

The Agency established an advisory group to guide the implementation of the recommendations of the HSURC working group. The Advisory Committee for the PPCC was tasked with providing advice on the planning, design, implementation, and evaluation of an organized population-based cervical cancer screening program with membership drawn from a wide variety of health professionals and stakeholders.[43] The Advisory Committee also has four subcommittees: Program Management, Recruitment Strategies; Quality Assurance, and Program Infrastructure.

Additionally, a task force was engaged at the request of Saskatchewan Health in February, 1998, with a mandate to advise on the design and implementation of an organized cervical cancer screening program for Saskatchewan. The task force presented its recommendations to the Saskatchewan Cancer Agency Board of Directors and Saskatchewan Health.[44] The Government of Saskatchewan gave its approval of the new program in 2002.[45]

I understand that in the early stages of development of the screening program there was consultation with Saskatchewan women. In 1994 there were focus group interviews *"to determine what they know about cervical cancer and why some women do not participate in screening, and identify possible ways to increase participation"*.[46] Forty-six focus groups were held in six southern health districts and 4 communities in northern Saskatchewan.

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[43] Final Report, supra, note 2, page 6
[44] Ibid, page 3
[45] The Saskatchewan Cancer Agency Annual Report 2003-2004 (available online: http://www.scf.sk.ca/AnnualReport/Saskatchewan%20Cancer%20Agency%202003-04%20Annual%20Report.pdf), page 10 (hereinafter "Annual Report 2003-2004")
[46] HSURC, supra, note 35, page 2

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

C. Preparations for the PPCC (cont'd)

At that time HIPA had not been introduced in the Legislative Assembly and it does not appear that the question of an opt-out was specifically discussed in those focus groups. There were no focus groups held subsequent to January, 1997, as the plan for the PPCC evolved and the major elements of the program including mandatory registration were resolved. There was no solicitation of public submissions, no public hearings, and no opinion surveys. It is important to recognize that Saskatchewan women are at least as important a stakeholder as any of the provider groups well represented on those advisory bodies. In my view, the public consultation was inadequate to properly canvass the views of Saskatchewan women on the aspects of compulsory registration and no right to opt-out.

The actual implementation of the PPCC did not take place until August, 2003.[47]

The primary responsibilities of the PPCC were to be:

- Educating women and health care providers about the importance of regular Pap tests;
- Reminding women when they are overdue for their regular Pap tests;
- Notifying women of their results;
- Encouraging appropriate follow-up when required; and
- Comprehensive quality assurance.

[47] Annual Report 2003-2004, supra, note 45, page 10

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

C. Preparations for the PPCC (cont'd)

The recommendations utilized by the PPCC are from the *Programmatic Guidelines for Screening for Cancer of the Cervix.*[48] These guidelines were developed by the following: the Society of Canadian Colposcopists; the College of Family Physicians of Canada; the Canadian Society of Cytology; the Society of Gynaecologic Oncologists of Canada; and the Society of Obstetricians and Gynaecologists of Canada. These guidelines make recommendations as to the frequency of testing and when examination and treatment are necessary based upon testing results [abnormal (low and high grade), unsatisfactory, or normal results].

D. The Data Flow

The Agency receives data for purposes of the PPCC from two databases in Saskatchewan Health. One is the Person Registry System (PRS) and the other is the Vital Statistics database.

Saskatchewan Health advises that:

> *"Information is disclosed by Health from the PRS to assist the Cancer Agency prepare a mailing list that will allow the Agency to provide a service that may reasonably be expected to benefit the individual (informing them of screening programs, encouraging personal monitoring, checkups, etc.). Data contained within the PRS is more comprehensive than the registry maintained by the Cancer Agency in that the Agency's registry is primarily limited to cancer patients. The prevention program is targeted more broadly than just patients and therefore the Agency requires additional information (e.g. Women who have not been treated for cancer, women who are new to the province). The PRS data is provided to ensure the Cancer Agency has up-to-date lists of women within the program's target group.*[49]

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[48] Programmatic Guidelines, supra, note 36

[49] We are advised that the two large health regions also provide information about women who are not within the PRS.

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

D. The Data Flow (cont'd)

The information from the PRS is used to assist the Cancer Agency provide the following service to benefit to the individuals:

- *To inform women of the risks of cervical cancer and the benefits of regular Pap tests;*
- *To encourage follow-up test results as appropriate;*
- *To inform women when they are overdue for a Pap test; and*
- *To provide women with their Pap test results.*

. . .

Information is also provided from the PRS to assist with updating and verifying the accuracy of the existing registry at the Cancer Agency (including what was provided by Health in previous years disclosures)."

Vital Statistics informs the Cancer Agency of all deaths that are registered by Vital Statistics (including those that occur to persons who are not residents of the province). The personal information from the Registration of Death form that is released by Vital Statistics to the Cancer Agency is:

- *name (given, middle and surname),*
- *Sask Health Services no.,*
- *Vital Statistics death registration no.,*
- *treaty number (if Status Indian)*
- *band name (if Status Indian),*
- *sex,*
- *marital status,*
- *date of birth,*
- *age (at date of death),*
- *residence address,*
- *date of death,*
- *place of death, and*
- *cause(s) of death (immediate, antecedent and other)*

The information is used by [the Agency] to update its registry and verify the status of the persons on the registry."[30]

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[30] Letter from Privacy Officer, Director, Strategic Planning and Information Policy to OIPC dated January 11, 2005 [hereinafter "Letter from Privacy Officer"]

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

D. The Data Flow (cont'd)

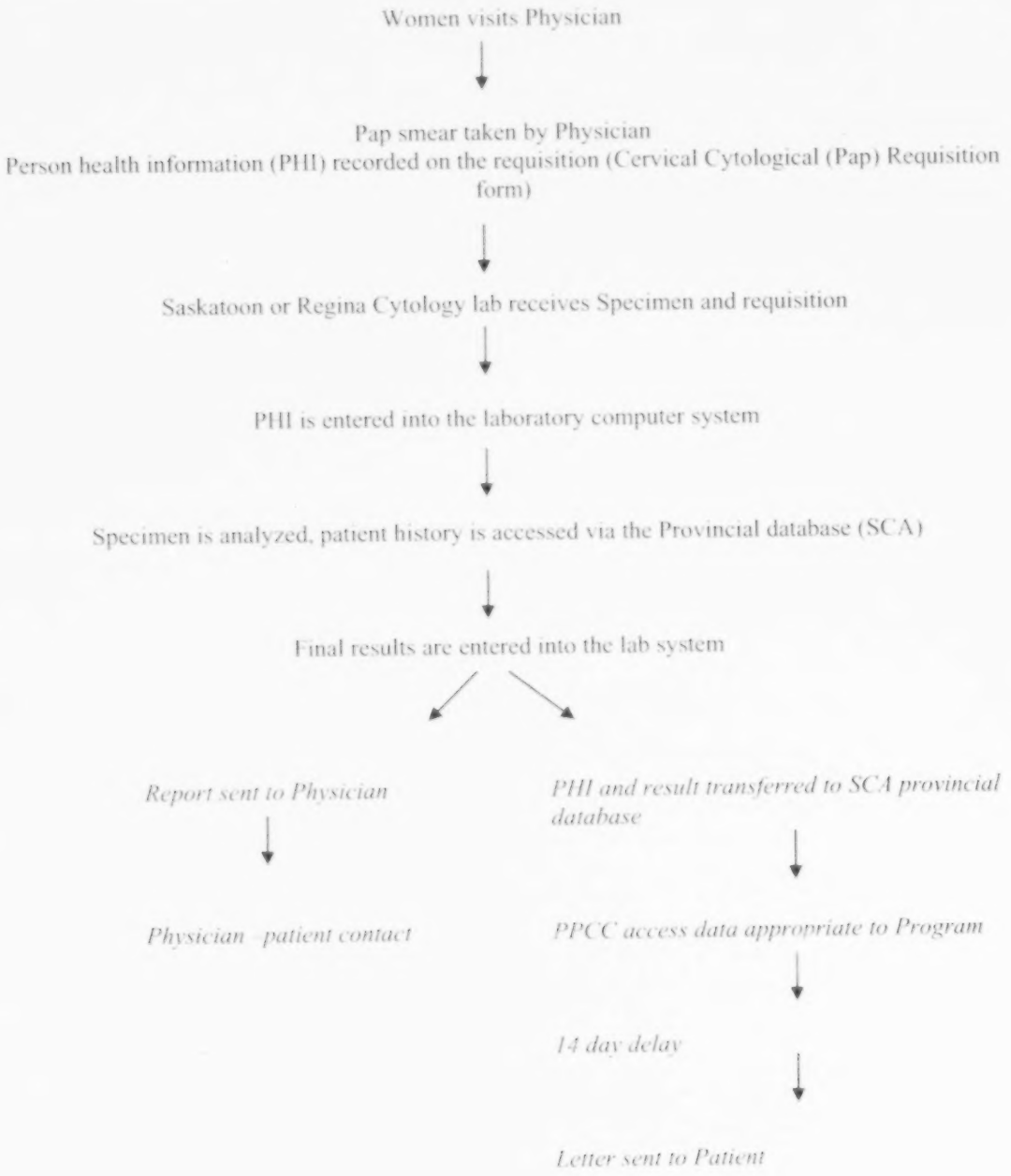
Vital Statistics has provided this information to the Cancer Agency since at least the early 1980s. There was no document to indicate a start of disclosure, however, (according to Saskatchewan Health) there has been a long standing practice of disclosure which is, if not an agreement, then it is an "arrangement".

The eligible population of women in this program are 18-69 years of age, alive with a cervix. All Saskatchewan women between the ages of 18-69, who have health care coverage or who have been identified by the Saskatoon Regional Health Authority and the Regina Qu'Appelle Regional Health Authority, are automatically enrolled in the PPCC. Non-eligible women include those under the age of 18, and over the age of 69 and/or women who have or have had cervical cancer. The Agency did not send out an introductory letter to all eligible Saskatchewan women to advise women of the PPCC.

Women who turn 18 years of age, or those that are overdue for a Pap smear are sent a reminder letter instructing them to make an appointment with their doctor.

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

D. The Data Flow (cont'd)


Women visits Physician
Pap smear taken by Physician
Person health information (PHI) recorded on the requisition (Cervical Cytological (Pap) Requisition form)
Saskatoon or Regina Cytology lab receives Specimen and requisition
PHI is entered into the laboratory computer system
Specimen is analyzed, patient history is accessed via the Provincial database (SCA)
Final results are entered into the lab system
Report sent to Physician
Physician – patient contact
PHI and result transferred to SCA provincial database
PPCC access data appropriate to Program
14 day delay
Letter sent to Patient

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

D. The Data Flow (cont'd)

All abnormal and unsatisfactory Pap test results are tracked to ensure that the women receive follow-up care by primary care providers in accordance with clinical practice guidelines. The PPCC receives histology data from pathology labs and links reports to abnormal cytology results. Repeat Pap tests are linked to the original abnormal results and/or unsatisfactory result. If the PPCC does not receive documentation that the follow-up has occurred, the PPCC will contact the GP and/or the colposcopist directly.

According to the Agency, results are communicated to women only after they have been sent to providers, and will not include clinical detail. Women are told either their test was normal (they will be advised to continue with regular periodic screening) or, there is a need for them to contact their physician/provider for follow-up. Fourteen days after the lab has notified their physicians of results, a letter is sent to the woman to notify her of her results. This is supposed to allow the physician time to contact the woman about her results. In a number of cases reported to our office, the letter from the Agency advising of an "abnormal result" arrived before they received a telephone call from their physician's office with that same information. Since some physicians only contact the patient if the lab results are abnormal, many women would get notice of the results via the contents of the letter sent by PPCC.

Prior to the establishment of the PPCC, it would have been the Cytology departments in the two large health regions that would have provided physicians with notification of all Pap test results. The laboratories also sent follow-up letters to physicians for patients who had abnormal results. These follow-up letters were a reminder to the physician that the original result indicated that the patient needed a repeat Pap test at that time and should not wait for the annual check-up.

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

D. The Data Flow (cont'd)

The primary intent of these follow-up letters was quality assurance and the secondary intent was to assist the physician with patient follow-up. We have been advised that this was an incomplete process from a follow-up and patient management perspective.

My understanding is that, in spite of the new role for the Agency database as the main repository for historical histology and cytology data, the source information and test results continue to be data generated initially and retained by the laboratories in the two large health regions. The pathologists, associate pathologists and cytotechnologists skilled in interpretation of Pap test results and related activities continue to do their work in those laboratories. They do that work subject to the *Canadian Society of Cytology Guidelines for Practice and Quality Assurance in Cytopathology*. We understand that quality assurance requires access and manipulation of retrospective historical, cytologic and histologic data. This historical data search now utilizes the PPCC database. The regions no longer provide physicians with a "patient follow-up" notification.

E. Agreements between the Agency and the RQRHA and SRHA

It is necessary to also assess the impact of a series of written agreements that have been created by the Agency and the two large health regions, Saskatoon and Regina Qu'Appelle. But first let us consider the recent historical practice for dealing with patient information regarding Pap specimen testing.

A single provincial database was established for cytology and histology records relating to the diagnosis and treatment of cervical cancer as recommended by HSURC. The cytology data is generated and stored by the RQRHA and SRHA cytology laboratories[51]. Histology data is generated by the same regions Histology laboratories.

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[51] Prevention Program for Cervical Cancer, TMC, Detailed Design Document, page 99

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

E. Agreements between the Agency and the RQRHA and SRHA (cont'd)

This database contains all historical cytology and histology records, and daily lab reports. Providers include the physician who takes the smears, then cytology labs analyze, colposcopy units is where treatment is delivered, and histopathology laboratories where diagnosis and treatments are confirmed.

Since 1994, the Cytology departments in RQRHA and SRHA contracted with a private corporation, MDS intRlab (MDS), for purposes of information management services. This entailed linking data from the two regions into a provincial database. The provincial database would ensure that the two large health regions would have a complete picture of each patient's cervical health. This would include client identifiers, health provider identifiers, cytology, histology, colposcopy, and other data related to Pap smear testing and follow-up.[52]

This arrangement with MDS was scheduled to end in the fall of 2004. In 2003, the RQRHA and SRHA laboratories began discussions on replacement of that system. Maintenance of a provincial database was deemed critical for the quality of the program. At approximately the same time, the Agency defined the PPCC and discussions between the Agency and the two regions began. There was a need to develop a new provincial database to share historical and future data.

To fill the anticipated void and to facilitate the cervical cancer screening program, a number of agreements were developed.

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[52] Data Sharing Schedule #3, Appendix C, Final, dated effective March 1, 2003.

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

F. Master Data Sharing Agreement

The Master Data Sharing Agreement dated March 1, 2003 describes, at a high level, the data sharing relationships between the RQRHA and the Agency. A parallel agreement was made between the SRHA and the Agency. It makes no explicit reference to the PPCC.

No term is specified for these agreements. They authorize data sharing in accordance with Schedules to be developed. It is left to the Schedules to identify the data elements to be shared and the purposes for which the data may be used by the parties.

This agreement includes a provision that:

> *"If new legislation is proclaimed into force relating to, or impacting on, the Data sharing contemplated by this Agreement and/or any Data Sharing Schedule, both parties agree to negotiate in good faith and in a commercially reasonable manner such further agreements, amendments or documents as reasonably required to ensure compliance with such legislation by both parties."* (page 3)

The agreement imposes obligations to limit use and disclosure and to safeguard the information.

G. Data Sharing Schedule #1

This agreement dated January 27, 2004, between the RQRHA and the Agency has a counterpart between the SRHA and the Agency. Data Sharing Schedule #1 identified that the operation of the PPCC requires access to the data provided by the RQRHA and the SRHA and stored on the PPCC server. This specifically addresses the PPCC and its need for laboratory data from the two regions. There is a detailed description of the data that will be disclosed by the region to the Agency. This includes "*Other data elements identified as being required by the* [Agency] *as the PPCC project develops.*" The Agency is permitted to "*access, use and disclose the Data: (a) for the purposes of carrying out the objectives of the PPCC; (b) for the purposes of providing patient care; and (c) as otherwise authorized pursuant to the Master Agreement.*"

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

H. Data Sharing Schedule #2

This agreement is also dated January 27, 2004, between the RQRHA and the Agency and has a counterpart between the SRHA and the Agency. This document states that "*In connection with the sharing of data described in Data Sharing Schedule #1, the RQHA wishes to engage the* [Agency], *in the capacity of an information management service provider, for the purposes of having the* [Agency] *warehouse the data elements described in Data Sharing Schedule #1 and this Data Sharing Schedule #2 on behalf of the RQHA.*"

This warehousing is intended to provide a comprehensive cytology and related histology database, which includes but is not limited to data required by the PPCC. It also describes the Agency as the information management services provider for all 59 data elements listed in that document. In preparation for the shift to the Agency from MDS the Regions wanted to ensure that there would be a source of data independent of MDS, namely the PPCC. At the time of that agreement, it had not yet been determined that the Agency would be the sole source of relevant data for the RQRHA and the SRHA. This agreement was expressly designed to enable the sharing of data necessary for the functioning of the PPCC.

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

I. Data Sharing Schedule #3

This agreement was signed by the Agency on June 29, 2004, and by the RQRHA on July 12, 2004. This agreement has a counterpart between the SRHA and the Agency.

In the High Level Overview portion of the document it is stated that the RQRHA now wishes the Agency to be the sole source of the cytology and related follow-up and that the purpose of this Data Sharing Schedule #3 is to confirm the terms and conditions by which the Agency will be the RQRHA's sole source of the Data.

Unless terminated earlier, the term of this agreement shall be for a period of one year, commencing June 1, 2004, and thereafter shall automatically renew for successive one year terms.

The Data includes all cytology and related follow-up (e.g. Histology and colposcopy) data comprising the PPCC database from time to time. The Data elements are listed in the document.

Clause C.2 provides as follows:

> *The parties acknowledge that the Services are intended to be provided in a collaborative manner for the mutual benefit of both parties. To that end, the parties agree that they will review, at least annually, the then current service arrangements and make reasonable adjustments or changes to the Services as mutually agreed upon.*

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

1. Data Sharing Schedule #3 (cont'd)

In the Appendix A Data Services it is stated that "*The PPCC application is a repository of the Data containing Pap screening results for Saskatchewan women (some Alberta/Manitoba) dating back to the early 1990's.*"

Data Sharing Schedule #3 explicitly declares that the "PPCC database" is the sole source of the 59 data elements. It also contemplates that the respective services of the parties are intended to be provided in a collaborative manner for the mutual benefit of both parties. Clearly, the Agency has a dual role – it provides information management services to the RQRHA and the SRHA and also is entitled to access some of the data for purposes of the PPCC.

Although some of the trustees have described the 59 data elements as the "provincial database" we think it more appropriate to use the term "PPCC database" consistent with this Schedule.

Although there are some similarities between the provincial database provided by MDS Labs prior to the fall of 2004 and the current PPCC database, the major difference would appear to be that MDS would have had no access to the provincial database as it existed at that time for its own purposes. It would have been exclusively an information management services provider. The PPCC, by virtue of the Master Data Sharing Agreement and Schedules, has the right to use and disclose the data in that PPCC database for its own purposes independent of the regions.

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

J. Commentary on Agreements

The reasons offered by the Agency for taking on this role can be summarized as follows:

- There are significant quality of care advantages. The data accessible by the Health Region labs from the PPCC system has better assurances in terms of quality, accuracy and completeness than was possible with the previous software.
- Using an outside (perhaps out of province or out of country) vendor could add risk from a security perspective.
- There is a significant cost saving to the Regions in that the data requirements for the PPCC encompass the vast majority of the data warehoused by the Agency. Therefore to have a separate vendor to warehouse the provincial database and then send a subset of the data to the PPCC would essentially double the cost to the health system.

K. Can a Woman withdraw from PPCC?

A woman currently is permitted to request that she will no longer be sent letters advising when she is due for a test and letters notifying her of Pap test results. Although some of the Agency material refers to this as an "opt-out", I find it is not an opt-out as that term is used in a privacy context.

That is apparent when one considers that notwithstanding her attempt to withdraw the following will still occur:

- She will not receive overdue or result notification letters;
- Her physician will receive follow-up communication from the Agency if there has been an abnormal or unsatisfactory result;
- All client cytology and histology information is maintained in the PPCC database.

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

L. Prevention Program for Cervical Cancer Prepared Chronology

The following is a chronological presentation of activities prepared by the PPCC:

Prevention Program for Cervical Cancer Progress To-Date

January 1997	Health Services Utilization and Research Commission, "A Comprehensive Approach to Cervical Cancer Screening"
February 1998	Established Task Force for Cervical Cancer Screening.
October 1999	Final Task Force Report submitted to Saskatchewan Health.
January 2000	Implementation Plan submitted to Saskatchewan Health for approval.
June 2001	Funding and approval to proceed with development of the screening program.
October 2001	Sk Society of Medical Laboratory Technologists conference presentation
November 2001	Advisory Committee for the Prevention Program for Cervical Cancer.
January 2002	PPCC education strategy – announcement of the Saskatchewan PPCC via Media Reports.
February 2002	POGO presentation
March 2002	Cancer Stem to Stern Conference presentation
April 2002	Selection of Software Vendor and Development of Program Design Document; Display at SAHO conference Display at Cancer Symposium.
May 2002	PPCC insert in SMA, College of Physicians and Surgeons professional newsletters (12,000); PPCC insert attached to SCA employee paystubs
June 2002	PPCC drafted an insert distributed through SMA newsletter to all physicians and to nurses registered with the Saskatchewan Registered Nurses Association.
July 2002	PPCC newsletter insert to Advanced Nurse Practitioners, Community Health Educators and Community Health Nurses; PPCC article in SSMLT laboratory newsletter; Development of brochures and letters begins
September 2002	Software Development; PPCC fact sheet distribution with SPBC mobile service to northern Sk

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

L. Prevention Program for Cervical Cancer Prepared Chronology (cont'd)

Prevention Program for Cervical Cancer Progress To-Date (cont'd)

October 2002	Displays at CIBC Run for a Cure; PPCC presentation with BCAS in Southey for Women's Health Day; ABCC gynecological Grand Rounds presentation; SSMLT conference presentation; TBS presentation
November 2002	C95 Radio Marathon display; PPCC provider update newsletter mailout to all physicians in Sk.
February 2003	POGO presentation
March 2003	PPCC brochures finalized (program, results and physican); Provider brochure sent with PPCC launch letter dated July 15, 2003 to 1,000 Saskatchewan practitioner, mailout included all other brochures for patients to be placed in reception areas/waiting rooms; Federal Women's Equal Opportunity "Road Map to Life" symposium presentation; Began enclosing PPCC brochures with SPBC recall letters
April 2003	Grand Rounds teleforum (Royal University Hospital)
May 2003	Swift Current District Medical Association Workshop presentation
June 2003	Finalize recruitment and recall letters; radio advertisements recorded in English, Cree and Dene; mailout with all PPCC information to all community health centres
July 2003	Historical Cytology Imported from RQHR and SHR. All health clinics and heath centres received packages of brochures for display. All radio stations and newsPapers ran articles and promos on the program – repeated November 2003 (87 newsPapers and 32 radio stations)
August 2003	Phase I – Daily cytology imports from RQHR & SHR; Result notifications to women; Age 18 information letters generated; Special mailout sent to northern clinics for distribution Mailout to all gynecologists and colposcopists
September 2003	Age 67-69 overdue letters generated (7,000) PPCC Fact Sheet Distribution with SPBC Mobile Service Northern Saskatchewan CME conference - Cervical Neoplasia
October 2003	One year and three year screening interval letters – started generating approximately 2,000/day Display at the Run for the Cure in Regina. SSMLT conference presentation Systems teaching to 3rd year medical students

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

L. Prevention Program for Cervical Cancer Prepared Chronology (cont'd)

Prevention Program for Cervical Cancer Progress To-Date (cont'd)

November 2003	Presentation at Red Earth for First Nation Women C95 Radio Marathon display PPCC print advertisement in all city and town newsPapers (87 newsPapers) PPCC radio advertisements on all radio stations in English and Cree and Dene for northern regions (32 radio stations) Brochures sent to College of Nursing for Distribution; PPCC Presentation at CME conference
December 2003	Mailout to all physicians regarding the intent to assume responsibilities for cytology result follow-up of all non-normal results; brochures for display also sent. ABCC Grand Rounds presentation on PPCC
Ongoing in 2003	Six gynecological presentations to residents and medical students
January 2004	PPCC information incorporated into CME website
February 2004	NewsPaper advertisements in northern Sk Papers (Eagle Feather & Sk Sage) PPCC presentation to Sk Community Health/Treatment/Home Care Nurses working in First Nations health facilities
March 2004	Presentation to Prince Albert Regional Women's Committee Privacy brochure was completed and included with letters to women Second presentation to to Sk Community Health/Treatment/Home Care Nurses working in First Nations health facilities Presentation to Riverbend Institution Correctional Services of Canada Regional Women's Committee Presentation at BCAS Sk AGM
April 2004	Phase II – Historical and daily histology data imports; Follow-up of abnormal and unsatisfactory results; Manual entry of all other histology reports; Manual entry of colposcopy reports. Presentation to Saskatoon City Hospital gyne staff
May 2004	Follow-up programmatic guidelines provided to U of R Women's Health Centre (requested) Presentation to Pheasant Rump First Nations Presentation to Ocean Man First Nations

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

L. Prevention Program for Cervical Cancer Prepared Chronology (cont'd)

Prevention Program for Cervical Cancer Progress To-Date (cont'd)

Spring 2004	Phase IV - Quality Assurance Reports. - Established the position of Privacy Officer – Heather Stuart assigned role on March 1, 2004. - To ensure compliance with *The Health Information Protection Act.* - Is responsible for the development, implementation, and evaluation of policies and procedures to protect the privacy and security of personal health information held by the Agency while ensuring that the information is accessible for administrative and research needs. January – June 2004, presentations
June 2004	Phase III – Web based application tested and in use by labs; Privacy Oversight Committee – created to monitor and provide direction on the development, implementation and operation of the Agency's Privacy Program. Tripartite letter (the RQHR, the SHR, and the PPCC) was sent to approximately 1000 primary care providers announcing the transfer of non-normal result follow-up to the PPCC from cytology labs located within the two health regions along with the follow-up guidelines for non-normal results Follow-up programmatic guidelines provided to U of S Women's Health Centre (requested) Presentation to Makwa Sahagaeihcan/Loon Lake First Nations Presentation to Primary Care Nurses conference
July 2004	New PPCC and SPBC display panels created Physician mailout regarding tripartite agreement with RQHR and SHR regarding follow-up guidelines
August 2004	Display at BCAS trade show NewsPaper advertisement in northern newsPaper (Sk Sage)
September 2004	SCA Privacy Committee was established in compliance with the Governance Model. SCA's Confidentiality Policy was approved by the SCA's senior management team on September 13, 2004. SCA Policy Number HR 501 approved September 13, 2004 Provided Regina Open Door Society with educational tools and materials Teleconference with Population Health Unit, Athabasca Health Authority, Keewatin Yatthe Health District and Mamawetan Churchhill River Health District (included all CHN's and CHE's from those areas) Finalize Release of Information forms and processes Provided educational tools and materials and Planned Parenthood in Regina

X THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)
(Background Information)

L. Prevention Program for Cervical Cancer Prepared Chronology (cont'd)

Prevention Program for Cervical Cancer Progress To-Date (cont'd)

October 2004	Presentation to Urban Development Conference in Saskatoon Display at CIBC Run for a Cure Print advertisement in Pure Woman Magazine (circulation approx 14,000) Presentation to Saskatoon Cancer Centre staff education rounds
November 2004	C95 Radio Marathon display SBCN - tour of North West communities with CHE's and CHN's to cancer screening - significant number of materials distributed at all stops Print advertisement in Pure Woman Magazine (circulation approx 14,000)
December 2004	Presentation and information session at Al Ritchie Community Centre Attended and formed partnerships at Open Door Society Workshop
January 2005	Editorial and advertisement in Star Phoenix Wellness Magazine Re-print advertisement in Pure Woman Magazine (circulation approx 14,000) PPCC update newsletter insert into SMA, College of Physicians and Surgeons and SRNA newsletter (approximately 12,000)
February 2005	Met with U of R Women's Health Centre to discuss SPBC and PPCC guidelines and provide information for their clinic PPCC Education & Recruitment committee meeting
March 2005	Display at U of R Kinesiology and Health Studies Faculty health and career fair Presentation at SAMRT conference Presentation at SIAST Nursing students cancer symposium
LETTERS PRINTED TO DATE (Aug 01 03 - Feb 28/ 05)	Physician follow-up low unsatisfactory - 552 Physician follow-up low grade - 1,231 Physician follow-up high grade - 526 Colpo follow-up letter - 97 18 year old notification letter - 19,579 67 year old letter - 7450 1 year recall letter - 216,928 3 year recall letter - 8,416 Reminder after recall letter - 79,260 Abnormal low grade - 6,724 Abnormal high grade - 2,817 Unsatisfactory - 1,431 Normal - 183,379

XI WHAT WE HAVE HEARD FROM SASKATCHEWAN WOMEN

A. Complaints

Our office has received more than 100 complaints from Saskatchewan women concerned about one or more aspects of the PPCC. Although we note that the Agency minimizes complaints from women about this program[53], we view this feedback as significant.

Our office, particularly in 2004, was not well known in the province and those women who did communicate with us were highly motivated to find ways to register their concern. If there were more than 100 women who took the time and effort to locate our office and then to register their concern by letter, fax, email or telephone, I expect there are many more Saskatchewan women who may have similar issues or misgivings with respect to the program who did not know where to take their concern.

Although the Agency in its latest Annual Report claims that "*... the vast majority of women contacted to date support this prevention and screening effort*"[54], I expect this is a conclusion drawn from the absence of more complaints rather than any objective attempt to measure the attitudes of women in this province.

As we discuss later in this report, at issue are rights of privacy that are guaranteed by the *Canadian Charter of Rights and Freedoms* and such rights are not dependent on the number of persons who complain.

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[53] Annual Report 2003-04, supra, note 45, page 6.
[54] Ibid., page 6

XI WHAT WE HAVE HEARD FROM SASKATCHEWAN WOMEN (CONT'D)

What follows is a highlighting of some of the concerns we have heard from Saskatchewan women. We have attempted to organize this feedback under the following headings:

- Letters and Brochure
- Lack of Concern
- Lack of Control
- Unethical Conduct
- Role of Physician
- Consent
- Legal Authority
- No Clear Information/Explanation
- Allocation of Resources

Letters and Brochure

"Intrusive and patronizing letters to these women telling them they have found out their Pap results and to ensure follow-up and participation in the program."

"…It is clear that this Prevention Program invaded that file and extracted information that I strongly feel that is NOT entitled to have."

"I know initially form [sic] *the experience in my own practice that the letters sent to women were easily identifiable by the envelopes. Many of my young patients who still live at home had not shared with their parents that they had a Pap smear because most young females have their first Pap after becoming sexually active. When the letter arrives in their house, it was quite obvious to the parents the significance of this information."*

"I have been separated for 5 years, but the envelope from the Cancer Agency with the results in it went to my ex-spouses residence."

"I have received two documents regarding Mammography and Pap smear. Both contain my name and file number."

"I was quite angry with this letter because somehow they had received my Pap test results without my consent."

"I am still opting out of getting medical tests done in Saskatchewan…The trust I had put into the confidentiality of medical test results has been violated…The SCA has no right to do that by sending out those invasive letters that boldly announce, "we know you were tested for this and that and the results was this and that."

XI WHAT WE HAVE HEARD FROM SASKATCHEWAN WOMEN (CONT'D)

Letters and Brochure (cont'd)

"My letter was opened inadvertently by another party, and my results then were able to be seen by another party. It is not right that this sort of information is being disseminated in such a fashion."

"I said the envelope had breached confidentiality...I stand by my statement that it is not the business of the postal workers, neighbours, parents, roommates or children to know anything about my cervix or its health...Have you ever considered the impact of a letter emblazoned with the word "cancer" and Mommy's name could do to a child?"

"...my parents received mail for me, with the return address being from your organization in BIG BOLD PRINTING!!!! My mother was so embarrassed that she ripped off the return address on the envelope so no one would see it sticking out on her purse. Since approximately 50% of Saskatchewan residents live in rural Saskatchewan, did it ever occur to you that people in the post office would personally know the addressee of the letter?...Since I had never heard of your organization before, I assumed that you had got my address from some mailing list and you were soliciting for money. So I told her to go ahead and open it. To our surprise were my lab results...I did discover that I had never changed my address with Sask Health and that's why my parents got my results."

"I am infuriated that my medical test results are being publicized this way"

"I was extremely upset to receive a notice earlier this year, from a third party, that I should have a Pap smear."

"Throughout the brochure, the tone implies that women have done this to themselves by having multiple sexual partners. What about the woman who is the victim of rape, the victim of sexual abuse, the woman who has been victimized within a relationship by infidelity."

Lack of Concern

"Many of the people I have talked to cannot even understand why I would be concerned."

Lack of Control

"For me, an even bigger concern than the actual breach of my privacy has been the responses that I have received from SHR and the Saskatchewan Cancer Agency. To me, the responses indicate an appalling lack of knowledge about personal privacy and confidentiality, a lack of respect for even the concept of privacy, and a lack of respect for the dignity of individuals (particularly women) and their competence to make informed decisions about their own bodies."

XI WHAT WE HAVE HEARD FROM SASKATCHEWAN WOMEN (CONT'D)

Lack of Control (cont'd)

"Why were no procedures developed to accommodate women who chose not to participate?"

"I did not request to be included in the PPCC and the PPCC/SCA has no ability to determine if I, as an individual, require their services."

"I have the right to expect and receive confidential diagnosis and treatment."

"Participation should be voluntary."

"I am concerned that I have been stripped of my "responsibility" and my right to make decisions on my own behalf…Saskatoon Health Region has assumed the right to enrol me in health programs and share my health information with whomever they deem should enter my "circle of care" without consulting my physician or me."

"I asked if he would stop the sharing of information until the issue of informed consent was resolved. He said he would not."

"If I do not want this information shared, currently my only option is to not have testing done."

"Who wants to have any type of test in this province when one does not know who will have access to the results? I, for one, will not have any tests in this province."

"I do not need to be monitored."

"My information is now in the computer system."

Unethical Treatment

"…when I expressed my desire to withdraw from the program, [Agency employee] *used scare tactics and fear to discourage me…I have seen no indication that they have any awareness of or training in ethics and best practice models.*

Role of Physician

"I am horrified and disgusted that someone other than my doctor is telling me what to do with my own body"

"I choose to share this information with a physician of my choice – not the Saskatchewan Cancer Agency"

XI WHAT WE HAVE HEARD FROM SASKATCHEWAN WOMEN (CONT'D)

Role of Physician (cont'd)

"I consulted with my doctor about this invasion of privacy, and she assured me that she had not authorized this release of information."

"I had underwent a Pap test…At that time, my doctor did not ask about releasing the results of my Pap tests to any organization. If she would have asked, I would have said no."

"My health records are between me and my Doctor…"

"I have since enquired and found out that my physician did not give out my personal information to them."

"My family doctor is being by-passed."

"…I went to see my doctor. She was confused on how your organization received my Pap results as all she submitted was a report saying that I did not need a colopscopy."

"Many like me will be horrified to get a letter from the Saskatchewan Cancer Agency informing them of their test results when they expect these to be communicated from their family physician. I do not think I am alone in feeling that this is highly personal and sensitive information. Nor I am alone in feeling that I do not need an NGO monitoring my care when my physician and I are very capable."

"What goes on with my body is my private issue and only my doctor should tell me what to do."

"When I called my physician to ask how the Cancer Agency got my personal health information, he did not know and was unaware of the program."

"At best, the program is a duplication of what my doctor, the lab and myself already accomplish."

"I have expected that what went on in my doctor's office was anything but private."

Consent

"I had submitted concerns regarding the Saskatoon Health Region sharing my personal health information with the Saskatchewan Cancer Agency without my knowledge or consent or the consent or knowledge of my family physician."

"This information was given without my knowledge or consent as is I believe in contravention of the Health Information Protection Act."

XI WHAT WE HAVE HEARD FROM SASKATCHEWAN WOMEN (CONT'D)

Consent (cont'd)

"According to the Saskatchewan Cancer Agency they cannot delete data they have obtained without my consent because they have "a contractual obligation to SHR and RQHR to maintain without modification or deletion, all cytology and histology records related to the diagnosis and treatment of cervical cancer."

"Getting informed consent from women to participate in PPCC would be very easy...Why should SHR not want to get informed consent...To-date, neither the Health Region nor the SCA has answered this question."

"...without my consent or prior knowledge, when there is no "need to know", and when informed consent could have been easily obtained."

"I have never given my physician or anyone else permission to release my confidential medical information to your organization or other third party."

"My concern is that my personal health information was shared with a third party without my consent or knowledge when there was no "need to know" and when obtaining informed consent could have been done easily and efficiently."

"I was also under the impression that my PHN was only to be used for invoicing medical professionals. I am extremely upset that my personal, private information is used in other ways, without my knowledge or consent."

"I gave permission to know [sic] *one to have access to my file and I consider this to be my personal concern..."*

"Consent was not obtained. Confidentiality has not been observed."

"I was never given the opportunity to consent to this program...That the CCPP does not allow an individual to revoke consent is a blatant contravention of the law...When I asked why they would not allow me to revoke consent, I was told that the labs needed to use the CCPP's database to track results. If lab results must be tracked in a database, I need you to answer the following question. Who looks after the database that holds HIV test results? Are individuals who go in for testing even aware of it? If there isn't one, why is there a need for a Pap test database."

XI WHAT WE HAVE HEARD FROM SASKATCHEWAN WOMEN (CONT'D)

Legal Authority

"[Regional Health Authority employee] indicated that she was obligated under Section 16 of the Cancer Foundation Act to release my health information to the Cancer Agency. When I asked her how a "patient" was defined under the Cancer Foundation Act, she reported she did not know...I was confused that they had made such an important decision about my personal health information and that of other women without familiarizing themselves with the law...I note that in this correspondence the Cancer Agency is no longer invoking Section 16 of the Cancer Foundation Act to legitimate their right to access my personal health information. They now refer to HIPA. I am curious about his change in the explanation."

"Could our government arbitrarily pass such a legislation and take away my right to my own medical records? I always thought my medical records stay confidential between me and my doctor."

"I do not believe any judge in Saskatchewan would deem all women "patients" under the Cancer Act."

"Is my level of privacy in Saskatchewan contingent on loopholes?"

"I have difficulty understanding the act as I do not have a legal background, but is this really the correct interpretation of primary and secondary, as intended by the act? It does not seem right to me that when my information has been transferred once (the primary purpose – transferred to the lab for testing), that the information can pretty well go anywhere after that and now be considered a secondary purpose for transfer – which seems to then require fewer standards to be met...shouldn't the purpose then be of benefit to me."

No Clear Information/Explanation

"The advertisement does not inform me that I am part of an ongoing monitoring and treatment program or that my "circle of care" has been extended to include the Saskatchewan Cancer Agency...Information on the website also does not provide information about how they will get my information or privacy issues...Did they even assess the proposed communication strategy."

"Will this database that has private information with names and addresses be used in research?"

"The day I received my letter, I called the supplied 1-800 number for the program...I then went to the Saskatchewan Cancer Agency's web-site. The site contained no information regarding the PPCC."

XI WHAT WE HAVE HEARD FROM SASKATCHEWAN WOMEN (CONT'D)

No Clear Information/Explanation (cont'd)

"From the comments related to this database, it appears that Saskatchewan Health also released health information related to me. What data was this? Do I not have the right to know what identifiable personal health information about me is released by whom and to whom and for what purpose."

"A week passes and still neither your organization nor the Saskatchewan Cancer Agency has returned my calls."

"Information on the website also does not provide information on how they will get my information or privacy issues. I have surveyed about 50 co-workers and friends. None of these, generally well educated and informed, women knew that they were enrolled in this program."

Allocation of Resources

"The money should be focused on those high-risk women not seeking services or who have limited access to services."

B. Reflections on this Feedback

The feedback suggests that to be identified as a woman with cervical cancer can be highly stigmatizing. Further, given that young women who are sexually active are at greater risk of cervical cancer, there may also be prejudice to a young woman to the extent that others are aware she is undergoing Pap testing. These features of cervical health may raise larger privacy issues than many other surveillance programs.

The PPCC was implemented before the Agency had set up the privacy and confidentiality pieces of the program. In other words, consideration of all relevant HIPA requirements and development of capacity to promptly, accurately and completely respond to complaints proceeded much more slowly than the transfer of lab results to the Agency and the issuance of letters to Saskatchewan women in the fall of 2003 and early 2004.

XI WHAT WE HAVE HEARD FROM SASKATCHEWAN WOMEN (CONT'D)

B. Reflections on this Feedback (cont'd)

Women with concerns were variously referred to their primary care provider or to their regions or to the Executive Director of the Prevention and Early Detection for the Agency. These women often received inaccurate, out-of-date or confusing and in some cases, conflicting information. For example, some women were told the authority was *The Cancer Foundation Act* and others were referred to *The Health Information Protection Act*.

Even when HIPA was cited as authority for the disclosure of lab information to the Agency, there was no indication of which sections were relied upon.

There apparently was not a clear and consistent understanding within the Agency of the difference between 'privacy' and 'confidentiality'. At its core, privacy is about control by an individual over her personal health information. Confidentiality policies and practices were represented to be a full answer to privacy concerns registered by some women. They clearly are not. Confidentiality is an important facet of privacy insofar as it relates to the way an organization deals with someone's personal health information once it comes into their custody or control. Rules with respect to keeping health information safe are not normally any satisfactory substitute for control by the individual.

We have also identified a significant gap in physician awareness of the mechanics of the program.

XI WHAT WE HAVE HEARD FROM SASKATCHEWAN WOMEN (CONT'D)

B. Reflections on this Feedback (cont'd)

In a discussion of patient consent in health research in the UK, the following statements appear:

> *"It is no less important to say here just because every other recent report on these issues has said it: A sustained and thoughtful campaign must be mounted to rebuild trust in the ways the NHS, healthcare professionals, and researchers, including academic, and commercial researchers, use personal data, protect the data, and derive value from the data.*
>
> *Trust will be nourished if the public understand what is done and why, and if health organisations and researchers understand the concerns and preferences of the public. At present in the UK many organisations are preparing brochures, posters, and videos, holding discussions with focus groups, and participating in forums on these issues."*[55]

It appears that we also have some distance to go in Saskatchewan to ensure that the trustees engaged in the PPCC understand the concerns and preferences of the public, and in particular the common complaints that have arisen. In our extensive dealings with Saskatchewan women who do not wish to participate in the PPCC, there is a recurring theme that they resent being told they have no choice and must be enrolled in the PPCC.

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[55] Lowrance, William W., "*Learning from Experience – Privacy and the Secondary Use of Data in Health Research*, London: The Neuffield Trust, 2002, page 66 [hereinafter called "Learning from Experience"]

XII PLACING HIPA IN A LEGAL CONTEXT

Since HIPA is a new statute that has never been interpreted by a Saskatchewan court of competent jurisdiction, it is appropriate to consider the common law that applied immediately before HIPA came into force September 1, 2003 to understand what has changed.

We note a useful review of the common law on consent and confidentiality in a recent Canadian publication.[56] The authors, Timothy Caulfield and Nola M. Ries, commented as follows:

> *"Existing Canadian case law provides patients with a legitimate expectation that health information about them will be kept confidential and not disclosed to third parties without permission. Canadian health law jurisprudence places a strong and clear obligation on health care providers to maintain the confidentiality of health information. For example, in Peters-Brown v. Regina District Health Board, a hospital was found negligent in the way it posted confidential health information- in this case, a list of individuals for whom body fluid precautions should be taken. This legal confidentiality obligation is amplified by ethical standards, such as the Canadian Medical Association's Health Information Privacy Code, which starts from the proposition that the "right of privacy" is fundamental in a free and democratic society and emphasizes a "patient's right to determine with whom he or she will share information and to know of and exercise control over use, disclosure and access concerning any information collected about him or her.*
>
> . . .
>
> *To a large degree, consent law in Canada flows directly from an application of the ethical principle of autonomy and concern with one's physical integrity. In Ciarleariello v. Schacter, the Supreme Court of Canada explicitly noted this connection:*
>
> > *It should not be forgotten that every patient has a right to bodily integrity. This encompasses the right to determine what medical procedures will be accepted and the extent to which they will be accepted...This concept of individual autonomy is fundamental to the common law and is the basis for the requirement that disclosure be made to a patient.[57]"*

[56] *Consent, Privacy and Confidentiality in Longitudinal, Population Health Research: The Canadian Legal Context*, Health Law Journal, 2004

[57] Ibid, pages 22-24

XII PLACING HIPA IN A LEGAL CONTEXT (CONT'D)

The leading Supreme Court of Canada authority on control over individual personal health information is *McInerney* v. *MacDonald*.[58] In that decision, Laforest J. for the majority of members of the Court concluded:

> "[M]*edical records contain information about the patient revealed by the patient, and information that is acquired and recorded on behalf of the patient. Of primary significance is the fact that the records consist of information that is highly private and personal to the individual. It is information that goes to the personal integrity and autonomy of the patient.*"

Justice La Forest concluded that ownership of the records was vested in the caregiver or institution that created the records. He focused on the right of a patient to examine and obtain copies of all documents in their file. His analysis turned on the special role of a physician and the special fiduciary duty owed by a physician to the patient. Part of that duty is to enable patient access to personal health information of that patient. Justice La Forest observed as follows:

> *"The doctor's position is one of trust and confidence. The information conveyed is held in a fashion somewhat akin to a trust. While the doctor is the owner of the actual record, the information is to be used by the physician for the benefit of the patient. The confiding of the information to the physician for medical purposes gives rise to an expectation that the patient's interest in and control of the information will continue."*[59]

In the Morgentaler decision, Justice BerthaWilson observed that "[A]*n aspect of the respect for human dignity on which the Charter is founded is the right to make fundamental personal decisions without interference from the state. This right is a critical component of the right to liberty.*"[60]

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[58] (1992) 2 S.C.R. 138 at paragraph 18
[59] Ibid, paragraph 22
[60] R. v. Morgentaler, (1998) 1 S.C.R. 30 at 166

XII PLACING HIPA IN A LEGAL CONTEXT (CONT'D)

The Ontario Court of Appeal stated as follows:

> *"The right to determine what shall, or shall not, be done with one's own body, and to be free from non-consensual medical treatment, is a right deeply rooted in our common law."*[61]

There are many other Canadian decisions that affirm this patient autonomy model of consent.

XIII IS THE COMMISSIONER ENTITLED TO CONSIDER THE *CHARTER OF RIGHTS AND FREEDOMS* IN INTERPRETING HIPA?

We note that this question was recently addressed by Mr. David Loukidelis, Information and Privacy Commissioner for British Columbia in his seminal report, *Privacy and the USA Patriot Act -- Implications for British Columbia Public Sector Outsourcing*.[62]

Commissioner Loukidelis, in commenting on submissions his office received, noted:

> *"...we acknowledge that Canadian courts require Charter values and rights to be considered in interpreting legislation such as BC's [Freedom of Information and Protection of Privacy Act] FOIPPA.*
>
> *Charter protections include the right to be secure against unreasonable search and seizure (section 8) and the right to life, liberty and security of the person (section 7). The Supreme Court of Canada has determined that section 8 guarantees the right to enjoy a reasonable expectation of privacy and protects individuals from arbitrary intrusion by government. This extends to the collection and use of personal information. The closer the information is to one's "biographical core"- such as information about one's health, genetic characteristics, sexual orientation, employment, social or religious views, friendships and associations-the greater is the obligation on government to respect and protect the individual's privacy. We have accounted for these Charter values and rights in interpreting [The Freedom of Information and Protection of Privacy Act] FOIPPA for the purposes of this report.*[63]"

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61 Arndt v. Smith (1997) 2 S.C.R. 539; Fleming v. Reid (1991), 82 D.L.R. (4th) 298 and Mallete v. Shulman (1990), 72 O.L.R. (2nd) 417 (Ont. C.A.); B.(R) v. Children's Aid Society of Metropolitan Toronto (1995) 1 S.C.R. 3159

62 *Privacy and the USA Patriot Act – Implications for British Columbia Public Sector Outsourcing*, Office of the Information and Privacy Commissioner for British Columbia, (available online http://www.oipc.bc.ca/sector_public/usa_patriot_act/pdfs/report/privacy-final.pdf) (hereinafter "Patriot Act")

63 Ibid, pages 16-17

XIII IS THE COMMISSIONER ENTITLED TO CONSIDER THE *CHARTER OF RIGHTS AND FREEDOMS* IN INTERPRETING HIPA? (CONT'D)

I note also the extensive discussion of the Charter and its treatment of privacy in the Report *Use of Cancer Patient Information for Surveillance Purposes*. As the authors state:

> *"All government action is thus subject to the Charter, including all federal and provincial legislation, but also other types of official action such as the activities of government employees and officers in their official capacity, administrative decisions, etc. The Charter is part of the Constitution and therefore part of the supreme law of Canada. This means that any law that is inconsistent with the Charter "is, to the extent of the inconsistency, of no force and effect."*[64]

The written material addressing privacy and confidentiality in health research is also helpful in considering the PPCC. Many of the issues around consent for research have some applicability in discussing privacy and confidentiality in the context of treatment and the uses of health information for diagnosis, treatment and care. The Canadian Institutes of Health Research, in one report, noted as follows:

> *"While health research is of great social importance, Canadians also highly value their rights to privacy and confidentiality. These rights are intimately connected with the right to respect for one's dignity, integrity and autonomy in a free and democratic society and are constitutionally enshrined in the Canadian Charter of Rights and Freedoms (Part I of the Constitution Act, 1982, being enacted as Schedule B to the Canada Act 19821, c. 11) and Quebec's Charter of Human Rights and Freedoms (R.S.Q. c. C-12). Privacy and confidentiality lie at the root of international and national ethics guidelines, as well as professional codes of conduct."*[65]

I find that I am required to consider the Charter in interpreting HIPA for purposes of this report. To paraphrase Commissioner Loukidelis in his report, where HIPA can be read in a way that conforms to the Charter and in a way that does not, we should adopt the interpretation that is Charter compliant.[66]

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[64] Use of Cancer, supra, note 22, pages 15-16

[65] Secondary Use of Personal Information in Health Research: Case Studies. November 2002, pages 5-6 [hereinafter "Secondary Use"]

[66] Patriot Act, supra, note 62, page 88. See also Bell Express v. Limited Partnership v. Rex, (2002) 2 S.C.R. 559 at paragraphs 28-30, 60-66 and Slaight Communications Inc. v. Davidson, (1989) 1 S.C.R. 1038 at 1077-78

XIV *THE CHARTER OF RIGHTS AND FREEDOMS*

We noted earlier that the Supreme Court of Canada has determined that all Canadians enjoy a right of privacy by virtue of the *Charter of Rights and Freedoms*.

We also note that a legislature is presumed not to have intended to exceed its jurisdiction and consequently if two different interpretations are open, the one that would leave the statute intra vires should be adopted.[67]

In the result, the privacy protection in the Charter provides an important context for consideration of the implications of the screening program. I have found that Chapter 8, *Privacy Under the Canadian Charter of Rights and Freedoms* in the British Columbia Commissioner's report on the *USA Patriot Act* to be very useful. I note that the Honourable Gerard V. La Forest, C.C., Q.C. served as special counsel to my British Columbia colleague. As a former member of the Supreme Court of Canada, Justice La Forest wrote a number of very important decisions concerning privacy.

To assess privacy protection requires consideration of three specific sections of the Charter: 8, 7 and 1.

A. Section 8

> *"Everyone has the right to be secure against unreasonable search or seizure*[68]*."*

In R. v. Mills, the Supreme Court of Canada considered whether counselling and therapeutic records of a sexual assault victim could be accessed by defence counsel for the man charged with assaulting the victim.

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[67] Driedger, Elmer A. *The Composition of Legislation*, Ottawa: Queen's Printer and Controller of Stationary, 1957, pages 127 - 128 [hereinafter "The Composition"]

[68] The Charter, supra, note 6

XIV *THE CHARTER OF RIGHTS AND FREEDOMS* (CONT'D)

A. Section 8 (cont'd)

For the majority, Justice McLaughlin (as she then was) stated:

> *"This Court has most often characterized the values engaged by privacy in terms of liberty, or the right to be left alone by the state. For example, in R. v. Dyment, [1988]2 S.C.R. 417, at p. 427, La Forest J. commented that "privacy is at the heart of liberty in a modern state". In R. v. Edwards, [1996] 1 S.C.R. 128, at para. 50, per Cory J., privacy was characterized as including "[t]he right to be free from intrusion or interference[69]".*

This interest in being left alone by the state includes the ability to control the dissemination of confidential information. As La Forest J. stated in R. v. Duarte, [1995] 1 S.C.R. 30, at pages 53-54:

> *"...it has long been recognized that this freedom not to be compelled to share our confidences with others I the very hallmark of a free society. Yates J., in Millar v. Taylor (1769), 4 Burr. 2303, 98 E.R. 201, states, at p. 2379 and p. 242:*
>
> > *It is certain every man has a right to keep his own sentiments, if he pleases: he has certainly a right to judge whether he will make them public, or commit them only to sight of his friends.*
> >
> > *These privacy concerns are at their strongest where aspects of one's individual identity are at stake, such as in the context of information "about one's lifestyle, intimate relations or political or religious opinions": Thomson NewsPapers, supra, at p. 517, per La Forest J., cited with approval in British Columbia Securities Commission v. Branch, [1995] 2 S.C.R. 3, at para. 62.*
> >
> > *The significance of these privacy concerns should not be understated. Many commentators have noted that privacy is also necessarily related to many fundamental human relations. As C. Fired states in "Privacy" (1967-68), 77 Yale L.J. 475, at pp. 477-78:*
> >
> > *To respect, love, trust, feel affection for others and to regard ourselves as the objects of love, trust and affection is at the heart of our notion of ourselves as persons among persons, and privacy is the necessary atmosphere for these attitudes and actions, as oxygen is for combustion.*

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[69] *R. v. Mills*, [1999] 3 S.C.R. 668, paragraph 79

XIV *THE CHARTER OF RIGHTS AND FREEDOMS* (CONT'D)

A. Section 8 (cont'd)

> *See also D. Feldman, "Privacy-related Rights and their Social Value", in P. Birks, etd., Privacy and Loyalty (1997), 15, at pp. 26-27, and J. Rachels, "Why Privacy Is Important" (`1975), 4 Philosophy & Public Affairs 323. This Court recognized these fundamental aspects of privacy in R. v. Plant, [1993] 3 S.C.R. 281, [page 723] where Sopinka J., for the majority, stated, at p. 293:*
>
> *In fostering the underlying values of dignity, integrity and autonomy, it is fitting that s. 8 of the Charter should seek to protect the biographical core of personal information which individuals in a free and democratic society would wish to maintain and control from dissemination to the state. This would include information which tends to reveal intimate details of the lifestyle and personal choices of the individual.* [Emphasis added]
>
> *That privacy is essential to maintaining relationships of trust was stressed to this Court by the eloquent submissions of many intervenors in this case regarding counselling records. The therapeutic relationship is one that is characterized by trust, an element of which is confidentiality. Therefore, the protection of the complainant's reasonable expectation of privacy in her therapeutic records protects the therapeutic relationship."*

In his analysis of this provision, Commissioner Loukidelis stated as follows:

> *"The right of privacy-specifically, an individual's right to a reasonable expectation of privacy -- is a core component of section 8 of the Charter, which guarantees the right of everyone in Canada to be secure against unreasonable search or seizure.*
>
> *Search or seizure need not involve an entry onto property or the forced taking of property. The invasion of a reasonable expectation of privacy is what constitutes the search or seizure. Surveillance that intrudes on reasonable expectations, whether or not it involves electronic or other devices, constitutes a "search' for the purposes of section 8.*
>
> . . .
>
> *A two-part analysis applies to section 8 of the Charter. The threshold question is whether an individual has a reasonable expectation of privacy in the circumstances. If not, section 8 is not engaged. If there is a reasonable expectation of privacy, the second question to be answered is whether the search or seizure was reasonable. A search or seizure is reasonable if it is authorized by law, the law itself is reasonable and the manner in which the search or seizure is conducted is reasonable.*
>
> . . .

XIV *THE CHARTER OF RIGHTS AND FREEDOMS* (CONT'D)

A. Section 8 (cont'd)

Whether or not there is a reasonable expectation of privacy in particular information is determined from various contextual factors, including the type of information involved:

> *[I]n order for constitutional protection to be extended, the information seized must be of a "personal and confidential" nature. In fostering the underlying values of dignity, integrity and autonomy, it is fitting that s. 8 of the Charter should seek to protect a biographical core of personal information which individuals in a free and democratic society would wish to maintain and control from dissemination to the state. This would include information which tends to reveal intimate details of the lifestyle and personal choices of the individual[70]."*

In determining whether or not the kind of information involved in the cervical cancer registry qualifies as personal health information to which a "reasonable expectation of privacy" would attach I find that the following comments of Commissioner Loukidelis are helpful:

> *"The question, in each case, is whether, by the standards of privacy that we can expect to enjoy in a free and democratic society, it is reasonable for government or its agents to intrude on privacy of place, person or information without first establishing reasonable and probably grounds on sworn evidence before an independent judge. Canadian courts constantly refine our understanding of the standards of privacy in a free and democratic society and they give those standards vitality with reference to new technologies that, if uncontrolled, have the potential to annihilate individual autonomy over when, how and to whom we reveal information about ourselves.*
>
> *In R. v. Dyment, the Supreme Court of Canada held that a sample of blood taken by a doctor for medical purposes from a bleeding and unconscious hospital patient is intimately personal and confidential, as is other information about a patient concerning his or her medical treatment. The use for other purposes of bodily substances provided for medical purposes is a profound violation of personal autonomy that infringes on reasonable expectations of spatial, personal and information privacy, as does the disclosure of specific medical care information without patient consent. In R. v. O'Connor and R. v. Mills, the Supreme Court of Canada established that an extremely high expectation of privacy also attaches to therapeutic counselling records. Also in this category, without doubt, would be pharmaceutical records of medications issued to a person for his or her medical care.*
>
> . . .

[70] Patriot Act, supra, note 62, pages 89-90

XIV *THE CHARTER OF RIGHTS AND FREEDOMS* (CONT'D)

A. Section 8 (cont'd)

> *Generally speaking, the expectation of privacy that surrounds the collection, use or disclosure of information is greater the nearer the information is to an individual's biographical core-such as information about one's health, one's genetic characteristics, sexual orientation, employment, social or religious views, friendships and associations. Yet other contextual factors are also important- such as whether records are produced in the ordinary course of a regulated activity and whether their secondary use for a prosecution is related to the regulatory regime involved. Also, as noted earlier, technological advances continue to make it easier and easier to integrate, share and mind data collected for all kinds of purposes from all kinds of sources. Interpreting our privacy rights in the Charter in light of these new technological capabilities-and increased government adoption of them-remains a developing frontier for Canadian courts.*[71]"

I agree with and adopt Commissioner Loukidelis' analysis. I have no difficulty finding cervical health information would be very near the biographical core of a woman living in this province.

B. Section 7

> *"Everyone has the right to life, liberty, and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.*[72]"

Commissioner Loukidelis, in his report, made the following comments:

> "*Section 7 of the Charter gives everyone the right to life, liberty and security of the person-rights that may only be infringed in accordance with the principles of fundamental justice. The privacy guarantee against unreasonable search and seizure in section 8 of the Charter is an application of the broader principles of fundamental justice that are referred to in section 7 and must be accommodated by a search or seizure that is reasonable.*
>
> *The right of privacy in terms of the physical integrity and dignity of one's body and the therapeutic care of one's psychological wellbeing is present in the security interest in section 7. There is also a still-emerging view that, because individual privacy lies at the heart of what it means to be free, the right of privacy is part of the liberty interest in section 7.*

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71 Ibid, Pages 91 to 93

72 The Charter, supra, note 6

XIV *THE CHARTER OF RIGHTS AND FREEDOMS* (CONT'D)

B. Section 7 (cont'd)

> *The right of privacy in section 7 of the Charter may be a particularly important source of constitutional protection in circumstances where Canadian authorities permit, or are instrumental in permitting, an intrusion on the reasonable expectation of the privacy of Canadians, but where section 8 does not apply because there is no search or seizure by a Canadian government.*[73]"

C. Section 1

> *"The Canadian Charter of Rights and Freedoms guarantees the rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.*[74]"

The burden of proving that a limitation is reasonable rests upon the government.

In determining what is a reasonable limit the Supreme Court of Canada has developed a two part test[75] or the "Oakes test":

> *"(1) Is the objective of government in limiting a right of sufficient importance to Saskatchewan to justify such a limitation?*
>
> *(2) The limit must satisfy the following criteria:*
>
> *(a) it must be rationally connected to the Saskatchewan government's objective and not arbitrary;*
>
> *(b) it should impair the right as little as necessary to achieve the government objective;*
>
> *(c) the limit must be proportional to the benefits that accrue from achieving the objective i.e. "the cure cannot be allowed to be more harmful than the disease".*"[76]

Madam Justice Wilson of the Supreme Court has observed that the significance of the Oakes decision is that *"The Court decided in Oakes that a balancing of interest was required, the interest protected by the guaranteed right and the broader interest of the public as perceived by the government enacting the legislation."*[77]

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[73] Patriot Act, supra, note 62, page 93
[74] The Charter, supra, note 6
[75] The Queen v. Oakes, (1986) 1 SCR 103
[76] *The Charter of Rights*, Ian Greene, James Lorimer & Company, Toronto, 1989, page 55
[77] *The Charter: Ten Years Later* -- Proceedings of the April 1992 Colloquium of the Canadian Bar Association and the Department of Justice of Canada in Ottawa, page 94

XV STATUTORY AUTHORITY FOR THE PREVENTION PROGRAM FOR CERVICAL CANCER

The principal law that applies to the PPCC program is *The Health Information Protection Act* (HIPA).

There is no purpose clause in HIPA. There is a lengthy preamble to the Act as follows:

> *WHEREAS the Legislative Assembly recognizes the following principles with respect to personal health information:*
>
> *THAT personal health information is private and shall be dealt with in a manner that respects the continuing interests of the individuals to whom it relates;*
>
> *THAT individuals provide personal health information with the expectation of confidentiality and personal privacy;*
>
> *THAT trustees of personal health information shall protect the confidentiality of the information and the privacy of the individuals to whom it relates;*
>
> *THAT the primary purpose of the collection, use and disclosure of personal health information is to benefit the individuals to whom it relates;*
>
> *THAT wherever possible, the collection, use and disclosure of personal health information shall occur with the consent of the individuals to whom it relates;*
>
> *THAT personal health information is essential to the provision of health services;*
>
> *THAT, wherever possible, personal health information shall be collected directly from the individual to whom it relates;*
>
> *THAT personal health information shall be collected on a need-to-know basis;*
>
> *THAT individuals shall be able to obtain access to records of their personal health information;*
>
> *THAT the security, accuracy and integrity of personal health information shall be protected;*
>
> *THAT trustees shall be accountable to individuals with respect to the collection, use disclosure and exercise of custody and control of personal health information;*
>
> *THAT trustees shall be open about policies and practices with respect to the collection, use and disclosure of personal health information;*

XV STATUTORY AUTHORITY FOR THE PREVENTION PROGRAM FOR CERVICAL CANCER (CONT'D)

As indicated in our Investigation Report 2005-001[78], [63] and [64], in the absence of a purpose clause in the Act, we will be guided by the preamble in interpreting and applying the provisions of this Act. We are however mindful of the comments of a former Saskatchewan Deputy Minister of Justice as follows:

> *"Granted that a preamble can sometimes assist in the construction of a statute, the chances are equally good that it will create a doubt or ambiguity. A statute may be clear enough, but a loosely worded preamble may drive a court to an interpretation that cannot reasonably be sustained by the statute itself.*
>
> *Then, too, there is always the danger that a preamble will be used to justify the measure politically rather than to explain its real object or purposes: the preambles to the statutes enacted in England during the reign of Henry VIII are good illustrations of political preambles."*[79]

For purposes of HIPA, Saskatchewan health regions, physicians and the Agency are "trustees" as defined by section 2(4). The information on Saskatchewan women collected, used and disclosed by PPCC is "personal health information" as defined in section 2(m). This includes information with respect to the physical health of an individual, information with respect to a bodily substance derived from the testing or examination of a bodily substance of an individual, information collected in the course of providing health services to an individual and registration information.

There are two kinds of statutory obligations. There are specific requirements for collection, use, disclosure, security and access of personal health information. In addition there are a number of general duties of a trustee.

Let us first consider the general statutory duties of a trustee.

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[78] Saskatchewan Information and Privacy Commissioner (available online: http://www.oipc.sk.ca/Reviews_files/Investigation%20Report%20No.%202005-001%20-%20File%20070-2004.pdf)

[79] The Composition, supra, note 67, page 94

XVI GENERAL DUTIES OF A TRUSTEE

Part II of HIPA sets out a number of general rights to which any Saskatchewan resident is entitled. For example, if consent is required[80], the consent:

(a) Must relate to the purpose for which the information is required;
(b) Must be informed;
(c) Must be given voluntarily; and
(d) Must not be obtained through misrepresentation, fraud or coercion.
[Section 6]

An individual has the right to revoke his or her consent at any time. A trustee is obligated to take all reasonable steps to comply with a revocation of consent promptly after receiving the revocation. [section 7]

Section 9 provides as follows:

"9(1) An individual has the right to be informed about the anticipated uses and disclosures of the individual's personal health information.

(2) When a trustee is collecting personal health information from the subject individual, the trustee must take reasonable steps to inform the individual of the anticipated use and disclosure of the information by the trustee.

(3) A trustee must establish policies and procedures to promote knowledge and awareness of the rights extended to individuals by this Act, including the right to request access to their personal health information and to request amendment of that personal health information."

A trustee must take reasonable steps to ensure that the trustee is able to inform an individual about any disclosure of that individual's personal health information made without the individual's consent after the coming into force of this section. [section 10] Section 10 does not apply to the disclosure of personal health information for the purposes or in the circumstances set out in subsection 27(2). [section 10(2)]

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[80] Consent is "deemed" and therefore effectively not required for disclosure of personal health information for the purpose for which the information was collected by the trustee or for a purpose that is consistent with that purpose or for the purpose of arranging, assessing the need for, providing, continuing, or supporting the provision of, a service requested or required by the subject individual. [Section 27(2)(a) and (b)]

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

An individual has the right to request access to his or her personal health information and to request an amendment of that record. Finally, an individual has the right to apply to the Commissioner to request a review of an action taken, or a decision made, by a trustee with respect to the individual's personal health information.

In addition, there are a number of additional duties imposed on trustees.

> *"16 Subject to the regulations, a trustee that has custody or control of personal health information must establish policies and procedures to maintain administrative, technical and physical safeguards that will:*
>
> *(a) protect the integrity, accuracy and confidentiality of the information;*
> *(b) protect against any reasonably anticipated;*
> *(i) threat or hazard to the security or integrity of the information*
> *(ii) loss of the information; or*
> *(iii) unauthorized access to use, disclosure or modification of the information; and*
> *(c) otherwise ensure compliance with this Act by its employees"*

Our office in past reports has concluded that section 16 requires that a trustee establish written policies and procedures.[81]

A trustee, in collecting information, must take reasonable steps to ensure that the personal health information is accurate and complete. [Section 19]

In the case where personal health information is disclosed to another trustee, the 'receiving trustee' is subject to the same duties with respect to that information as the trustee that discloses the information. [Section 20]

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[81] Saskatchewan Information and Privacy Commissioner, Reports H-2004-001, 2004-006 and Investigation Report 2005-001 (available online at www.oipc.sk.ca under the tab "*Reports*")

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

There is an overriding requirement that collection, use and disclosure be limited on a need-to-know basis.

> *"23(1) A trustee shall collect, use or disclose only the personal health information that is reasonably necessary for the purpose for which it is being collected, used or disclosed.*
>
> *(2) A trustee must establish policies and procedures to restrict access by the trustee's employees to an individual's personal health information that is not required by the employee to carry out the purpose for which the information was collected or to carry out a purpose authorized pursuant to this Act.*
>
> *(3) Repealed.*
>
> *(4) A trustee must, where practicable, use or disclose only de-identified personal health information if it will serve the purpose."*

I note that there is a provision that permits the Cabinet to exempt any activities of a trustee from the application of HIPA. Section 65 provides as follows:

> *"65(1) The Lieutenant Governor in Council, on the recommendation of the minister, may, by order made within the first five years after the coming into force of this section, exempt any specified activities of a trustee from the application of this Act or any provision of this Act where:*
>
> *(a) in the minister's opinion, the implementation of all or any provision of this Act will cause undue hardship to a trustee; and*
>
> *(b) the minister is satisfied that the exemption will not have a significant impact on the interests of individuals whose personal health information is in the custody or control of the trustee.*
>
> *(2) An order pursuant to subsection (1) must specify a date on which the exemption expires."*

I note that this section has not been invoked by the Saskatchewan Cabinet in respect of the PPCC.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

I also note that, in cases where express consent is not required by HIPA, there is no general requirement similar to the provision in Alberta's *Health Information Act* section 58(2). That provides as follows:

> *"58(2) In deciding how much personal health information to disclose, a custodian* [equivalent to trustee in HIPA] *must consider as an important factor any expressed wishes of the individual who is the subject of the information relating to disclosure of the information, together with any other factors that the custodian considers relevant."*

In other words, if HIPA does not require consent for any given disclosure, there is no requirement for a trustee to consider at all any expressed wishes of the individual who is the subject of that particular disclosure.

A. Have these General Duties been met?

The test of a "reasonable expectation" of privacy of the individual that has been developed by the Supreme Court provides some interesting challenges when it is applied to the Saskatchewan health care context. In some of the complaints we have received, there is a certain naiveté as to health information sharing practices. It appears that at least some women expect that their health information remains in hard copy records under the direct and exclusive control of their family physician.

In fact, personal health information is shared quite widely in this province. Physicians can only be paid by the province if certain billing information, including limited patient information, is provided to Saskatchewan Health. Regional health authorities may require information to provide a range of health services to complement services provided by the family physician including laboratories, specialist assessment and special clinics. The College of Physicians and Surgeons may require disclosure of certain information to oversee professional conduct of its members.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

A. Have these General Duties been met? (cont'd)

Quality assurance committees may require access to personal health information. Private health insurance providers may require certain personal health information in order to process claims. I suspect that many Saskatchewan residents did not have a good understanding of health information sharing practices prior to HIPA coming into force.

So, does that kind of extensive sharing of personal health information suggest that there should be no reasonable expectation of privacy when it comes to information about a woman's cervical health moving to the Agency for purposes of the PPCC? I conclude that it does not for four reasons:

1. Information about a woman's cervical health is particularly sensitive information in respect to which she would have a reasonable expectation of privacy.
2. The PPCC's practice of inserting the Agency into an active role of interacting with women who do not have cervical cancer is a very new development.
3. The new interactive role for the Agency has not been satisfactorily communicated to all Saskatchewan women.
4. The value added by the PPCC to a well-informed woman with a competent family physician and who is regularly and appropriately tested for cervical cancer may be marginal.

I find that a Saskatchewan woman would have a reasonable expectation of privacy in respect of her cervical health information.

As noted above, the substitution of deemed consent or no consent in section 27(2) of HIPA for the kind of consent historically required by Canadian courts, diminishes the control that Canadian courts have accorded patients in the past over their personal health information. We therefore approach HIPA from the perspective that any trustee that wishes to rely on deemed consent must ensure that they are in compliance with both the general duties and the specific duties prescribed in this statute. The statute is a complete package and a trustee cannot take advantage of broader information sharing opportunities if it is violation of its general duties discussed above.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

I find that a trustee cannot rely on the provisions in HIPA for collection, use and disclosure of personal health information without express or implied consent in sections 26, 27 and 28 unless that trustee has first satisfied the general duties in sections 9, 10,16, 19, 23.

1. Saskatchewan Health

(i) Organization

There is a helpful description of this Department's organization privacy compliance in the Deloitte Touche Privacy Assessment.[82]

There is clear accountability in this Department. The Director, Health Planning/FOI Coordinator is accountable for managing the policies regarding personal information and overseeing compliance. This position has existed for more than 7 years.

(ii) Policy and Procedures

The Department has general policy and procedures including the *Information Management Policy for Saskatchewan Health* (1995), the *Acceptable Use and Security Policy* complemented by branch or application specific written policies for personal information.

There is Department policy to provide all new employees with an orientation that includes: (1) taking an oath of office which prohibits disclosure of any kind without authorization; (2) orientation to specific requirements of each position; (3) individual managers are tasked with responsibility to ensure staff are aware of policies specific to their areas. There have also been a number of awareness initiatives within the Department. There is a privacy element within the orientation of new staff. The Department represents to staff that it has a zero tolerance for unauthorized use or disclosure of confidential information and for unacceptable use of its IT resources.

[82] page 95-110. (available online at http://www.gov.sk.ca/service/publications/Privacy_Report.pdf)

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

1. Saskatchewan Health (cont'd)

(iii) Transparency

The precise type of personal health information collected by Saskatchewan Health and then disclosed to the Agency was described in detail earlier in this Report.

It does not appear that Saskatchewan Health has communicated to the 300,000 Saskatchewan women who are the target group for the PPCC clear information about the anticipated uses and disclosures of their personal health information by Saskatchewan Health to the Agency. I find that when the disclosure concerns the kind of sensitive information at issue in this investigation Saskatchewan Health should be proactive in communicating the intended disclosure at the time information is collected, and, if not at the point of collection, as soon as practical after that point. In this case, I understand that the relevant personal health information may have been collected many years earlier. If that is the case, then the time to advise Saskatchewan women in the target group would have been at the time the PPCC was rolled out in the summer and fall of 2003.

Saskatchewan Health's website should contain clear information on its role in supporting the PPCC.

I note that in one Agency brochure, *Cervical Screening - The Program*, the following appears:

> *"Based on the demographic information provided to the Prevention Program for Cervical Cancer from Saskatchewan Health, letters will be sent to Saskatchewan women when they turn 18 years of age.* [emphasis added]

All Saskatchewan women have not received that brochure. That information does not appear on the Agency's website.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

1. Saskatchewan Health (cont'd)

(iii) Transparency (cont'd)

Saskatchewan Health sends change information from the PRS (i.e. what has changed) to the Agency on a daily basis for females ages 18-69. In December, Saskatchewan Health sends the information on females who turned 18 in the calendar year as well. Saskatchewan Health also gives the Agency information on those females ages 12-17 and 70-75 who are identified by the Agency as being registered in the PPCC. In the case of the Vital Statistics data, the transfers are in accordance with the long-standing practice. Staff does not transfer data without appropriate authorization from management and in accordance with agreed upon schedules for updates.

I recognize that there is some limited information available on the department's website: www.health.gov.sk.ca/ph_br_health_leg_hipamain.html. I have not seen this site advertised in material to the 300,000 Saskatchewan women involved with the PPCC and in fact the site appears more designed to assist trustees than to inform individuals. On that website, the following appears:

> *"For an overview document describing the requirements for consent under the Act for the collection, use and disclosure of personal health information click here: Overview of Consent Requirements in The Health Information Protection Act (This document is currently being updated and will be posted as soon as it is available.)"*

As recently as April 19, 2005, this overview document was not available on the website.

There is no reference on the website to any kind of a Help Line that could be accessed by a citizen by phone, fax or email.

Saskatchewan Health is in a special position. It is a trustee along with many other organizations. It is also however Saskatchewan Health that is responsible for administration of HIPA. In other words, it has a leadership role in assisting other trustees in their statutory compliance efforts.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

1. Saskatchewan Health (cont'd)

(iii) Transparency (cont'd)

I recognize that Saskatchewan Health has spearheaded a consultative project with health regions and the Agency known as the Chief Information Officer Privacy Forum (CIO Privacy Forum). The purpose is to assist them in developing policy and materials. We have seen a number of brochures and posters that resulted from that process. Saskatchewan Health, however, is also a trustee in its own right and cannot rely on other trustees to communicate to the women of this province what happens with their registration information that is disclosed by the Department to the Agency. The information materials ideally would involve brochures with reference to more extensive material that ought to be available on the Department's website.

2. Health Regions

(i) Organization

Both of the two large health regions have designated Privacy Officers with responsibility for HIPA compliance. Given the size and complexity of these two organizations, we have focused only on those administrative features relevant to the PPCC. In other words, our focus has been on the laboratories. As noted earlier, I spent time in Saskatoon City Hospital meeting with the team that does the PPCC related work. I have also gathered materials from the Regina Qu'Appelle Region.

This office has not identified any concerns with respect to the existence of appropriate leadership in the two regions on the privacy file or with respect to the existence of appropriate policies and procedures as contemplated by section 16 of HIPA.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

2. Health Regions (cont'd)

(ii) Policy and Procedures -- Saskatoon Regional Health Authority

The key relevant policy is the Saskatoon Regional Health Authority's Laboratory Information System (LIS) Policy #LIS-711254030-1.

There are clear limitations on the use and disclosure of personal health information and reference to district policy that requires patient confidentiality must be maintained at all times.

I was furnished with detailed information on the screening process before anyone can obtain LIS access. This includes reference to the security level assignment given to the applicant. The individual must sign the LIS Training Confidentiality Sign-Off Form after they have received their training that includes information on confidentiality. Non-lab staff access to part of the LIS is carefully monitored and the staff are pre-screened. This would require a formal request from the department head to the Medical Director of Laboratory Medicine for his consideration.

The region has developed a (LIS) Security Access Acknowledgment document. This is a formal notice to hospital staff that require direct access to the LIS. This documents the authority, the information accessed, and the date of the request. Before anyone is granted access to the LIS they must complete a Security Authorization form. They will be given user-training by a staff member with LIS access.

The System Administrator of LIS deals with any SRHA Information Technology requests for access to the LIS system at the Unix level.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

2. Health Regions (cont'd)

(ii) Policy and Procedures -- Saskatoon Regional Health Authority (cont'd)

The system is protected by passwords, User IDs, permission categories for users and options and an automatic exit from the system when a terminal remains idle for 5-10 minutes, depending on the module and option. Passwords comply with the SRHA IT security policy. A member of the LIS Support team, provided appropriate authorization is received, can change the permission categories for user access to various functions. Review of system access is done on an annual basis by the LIS system administrator or on an ad hoc basis if a security problem is detected.

Each cytology technologist uses the SRHA Laboratory Information system to report results on Pap smears and other cytology specimens. They also use the PPCC Web Query program to look up previous cases for diagnostic purposes. They were trained on the use of the PPCC Web Query program and had to sign a Saskatchewan Cancer Agency System Access Privacy Pledge form before they received user ID and password.

Cytology data is transmitted from the SRHA server to the Agency server daily using File Transfer Protocol via a secured VPN tunnel with static IP addresses on both sides. Cytology technologists access PPCC Web Query via the VPN tunnel also with static IP addresses.

SRHA Cytology conforms to the guidelines for practice of the Canadian Society of Cytology. They are inspected by the Saskatchewan Program for Quality Assurance. This program is a program of the College of Physicians and Surgeons of Saskatchewan. SRHA Cytology also participates in external proficiency testing programs in cytology.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

2. Health Regions (cont'd)

(iii) Policy and Procedures --Regina Qu'Appelle Regional Health Authority

Patient confidentiality policies are reviewed by staff at region and site orientation sessions conducted by the Education Services staff. These policies include Policy number 1.1.5 approved on June 6, 2000, that would be applicable to all RQRHA employees and associates.

For the RQRHA, staff that require use of any region computer systems there are policies in place on who can request training and access to these systems. Policy 1.1.5b would be relevant. At the training session, the IT System Access Confidentiality form (IT Security form (IT Security form 5.4.03) is reviewed and signed by users. All users have to complete the training before User IE and password is assigned.

The RQRHA laboratories have orientation policies (Lab Orientation Program) for all lab staff. Staff members that use the Lab Information System must sign a Lab Information System Security form (LIS Employee Security Form) and receive the proper training before access is granted. Each lab user has his or her own unique user ID and password for access to the system.

Each Cytology technologist uses the RQRHA Laboratory Information system to report results on Pap smears and other cytology specimen. They also use the PPCC Web Query program to look up previous cases for diagnostic purposes. They were trained on the use of the PPCC Web Query program and had to sign a Saskatchewan Cancer Agency System Access Privacy Pledge form before they receive user ID and password.

Cytology data are transmitted from the RQRHA server to the Agency server daily using File Transfer Protocol via a secured VPN tunnel with static IP addresses on both sides. Cytology technologists access PPCC Web Query via the secured VPN tunnel also with static IP addresses.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

2. Health Regions (cont'd)

(iii) Policy and Procedures --Regina Qu'Appelle Regional Health Authority (cont'd)

RQRHA Cytology conforms to guidelines for practice of the Canadian Society of Cytology. They also participate in the Quality Assurance in cytology program. The RQRHA laboratories are inspected and accredited by the College of American Pathologists and participate in external proficiency testing programs in all disciplines offered by the College, including Cytology.

(iv) Transparency

The two large health regions operate the laboratories in Saskatoon and Regina which process the majority of the Pap specimens collected throughout the province. It is the regions that do the examination of the specimens and provide expert assessment and diagnosis to the physician based on that examination. The regions then submit personal health information to the PPCC database housed by the Agency. The PPCC accesses data required by the PPCC from that database. The regions do not need to interact with the women in the target population for purposes of the PPCC.

Section 20 of HIPA is engaged. That provides as follows:

> *"20(1) Where one trustee discloses personal health information to another trustee, the information may become a part of the records of the trustee to whom it is disclosed, while remaining part of the records of the trustee that makes the disclosure.*
>
> *(2) Where personal health information disclosed by one trustee becomes a part of the records of the trustee to whom the information is disclosed, the trustee to whom the information is disclosed is subject to the same duties with respect to that information as the trustee that discloses the information."*

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

2. Health Regions (cont'd)

(iv) Transparency (cont'd)

In the course of our investigation of the PPCC, we have received some complaints from women dissatisfied with responses they received from the two health regions. As best we can determine at this time, women who contacted the health regions to register objections or to seek more information were assisted to the extent that the laboratories could assist. The PPCC is however a program of the Agency and most of the complaints would likely have been referred to the Agency for follow-up.

I have determined that the two health regions have appropriate information to share with women about the PPCC and understand that any current requests for information or complaints received by the regions are being appropriately dealt with.

Given the size and complexity of the two large health regions and the range of health services they provide, we will in the future consider with all of the regional health authorities the most appropriate way for them to discharge the requirements of section 9 of HIPA. Pending those discussions, I make no recommendations to the two health regions with respect to section 9 and the PPCC.

3. Saskatchewan Physicians

(i) Organization

Saskatchewan physicians are trustees under HIPA and, at the same time, are subject to the federal *Personal Information Protection and Electronic Documents Act* (PIPEDA). The Privacy Commissioner of Canada and not our Saskatchewan office oversees PIPEDA. Both of these statutes require that a Saskatchewan physician have policies and procedures to ensure statutory compliance. We note that the College of Physicians and Surgeons has produced printed materials to assist Saskatchewan physicians with statutory compliance. Our office was consulted in the preparation of those printed materials and finds them appropriate to meet the requirements of section 16 of HIPA.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

3. Saskatchewan Physicians (cont'd)

(i) Organization (cont'd)

Our experience is that most of those physicians' offices that we have had occasion to deal with have tasked someone in the office with responsibility to ensure the requirements of HIPA are satisfied on an ongoing basis.

(ii) Policies and Procedures

As noted above, the printed materials produced by the College of Physicians and Surgeons are appropriate when they are utilized by a Saskatchewan physician. We are not in any position to comment on the extent to which individual physicians may or may not be compliant with the material developed by the College. We note, however, that we have received a number of complaints with respect to physicians and all of those appear to have been resolved after we referred the individual to the College pursuant to section 43(2)(f) of HIPA.

(iii) Transparency

Saskatchewan physicians play a pivotal role in the testing for cervical cancer. It is physicians who administer the Pap test to women throughout Saskatchewan and who then submit the specimen together with identifying information about the woman to the laboratories in either Saskatoon or Regina. In many cases, when women have questions about their Pap specimen results, they will want to discuss the implications with their physicians exclusively. The focus groups mentioned earlier apparently supported that view. Any resulting treatment will most likely be designed, coordinated and overseen by the physician.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

3. Saskatchewan Physicians (cont'd)

(iii) Transparency (cont'd)

I am mindful that the PPCC is not a program developed by the College of Physicians and Surgeons, although physicians have certainly been directly involved in the development of the PPCC. One could say that ownership of the PPCC is vested in the Agency and to some extent perhaps in its partners, the two large health regions and Saskatchewan Health. I find that the primary responsibility for communicating information about the PPCC to Saskatchewan women is that of the Agency.

What is the responsibility of physicians, if any, in terms of informing Saskatchewan women about the PPCC?

Section 9(2) requires the physician to take "*reasonable steps to inform the individual of the anticipated use and disclosure of the information by the trustee*" [emphasis added]. The key disclosure in terms of the PPCC is from the two large regional health authorities' laboratories to the Agency. It follows that such disclosure is not captured by section 9(2).

Section 9(1) and (3) however are more general. Section 9(1) focuses on the right of the individual without assigning responsibility for providing the information to the individual. Section 9(3) is a more general duty on a trustee "*to promote knowledge and awareness of the rights extended to individuals by the Act*" by means of policies and procedures.

Among the list of different kinds of trustees subject to HIPA, physicians may have a unique role in the collection, use and disclosure of personal health information. This is shaped by ethical practices and standards and by the Canadian common law. HIPA makes those ethical practices and standards relevant in interpreting HIPA.[83]

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[83] HIPA, supra, note 1, sections 27(3)(b) and 43(2)(f). See also *Placing HIPA in a Legal Context* (see XII of this report)

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

3. Saskatchewan Physicians (cont'd)

(iii) Transparency (cont'd)

The *Canadian Medical Association Health Information Privacy Code* (CMA Code) has this to say about physicians and their responsibility to patients:

> *"Governing principles and rules for health information must recognize the patient's right of privacy in health information, its highly sensitive nature, the circumstances of vulnerability and trust under which it is confided or collected, and the fiduciary duties of health professionals in relation to this information. The patient-physician relationship as defined by trust and a professional promise of confidentiality is a societal good worthy of protection.*
>
> *2.1 Principles and rules governing health information must recognize:*
>
> *a. its high level of sensitivity and protect the patient's right of privacy accordingly;*
> *b. that the principal purpose for confiding and collecting this information is to benefit the patient;*
> *c. that in the therapeutic context patients may be vulnerable and under duress, and must not be subjected to manipulation, coercion or exploitation;*
> *d. (d)that patients confide information to physicians and other health professionals under a very special trust, and that physicians and other health professionals have fiduciary duties to patients, including a duty to hold information in confidence."* (page 6)

Article 10.1 of the CMA Code provides as follows:

> *"Health information custodians must have transparent, explicit and open policies, procedures and practices, tailored to their practice setting, that seek to ensure that patients are provided with information about what can or must happen with their health information without their consent."* (page 14)

I note that, with the New Zealand cervical cancer screening program, the individual taking the Pap specimen is statutorily required to provide information to the woman about the program and her right in that country to opt-out of the program.

I find that a significant number of family physicians in Saskatchewan have not provided their female patients with sufficient information about the PPCC and how it operates. The complaints to our office have come from women in many different communities and many different health regions. In some cases, women advised us that their physicians had insufficient information about the PPCC to answer their questions.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

3. Saskatchewan Physicians (cont'd)

(iii) Transparency (cont'd)

Even though the key disclosure to the Agency is by the regions, and despite finding that the Agency has primary responsibility to inform Saskatchewan women about the PPCC, I find that the physician is also required under section 9 to provide information to the patient about the PPCC. Given the compulsory enrolment feature of the PPCC, it is clearly an anticipated disclosure of a woman's cervical health information within the meaning of section 9(1). The preferable time to provide information to women would be at the point of collection.

We are mindful that physicians tend to be extremely busy and there will be a concern there is insufficient time for them to discuss the PPCC with their patients. That should not preclude physicians' offices providing women with some literature on the program with particular emphasis on the future contact with these women that will be initiated by the Agency. We understand that neither the College nor the Saskatchewan Medical Association has produced any printed material about the PPCC for family physicians to distribute to their adult female patients.

The College advises that a two page article on the PPCC was included in its winter 2004 Newsletter. This would have been distributed to members in January, 2005. The article discusses the information management service provider role of the Agency as well as the PPCC. It clarifies that although women may choose to decline receiving letters from the PPCC, data will not be deleted from the system. This publication highlights a number of misconceptions about the PPCC and provides contact information for the Agency.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency

(i) New Legal Requirements

I am mindful that the PPCC actually started to be 'rolled-out' in the late summer of 2003 and that HIPA did not come into force until September 1, 2003. The Agency would, however, have received written notice from Saskatchewan Health in July, 2003, advising of HIPA's proclamation date.[84] I note also the long gestation period for the statute[85] and the fact that considerable training activities for HIPA compliance had been going on in the province for many months prior to September 1, 2003.

For those reasons, when the Agency started to implement the PPCC it should have been aware of the HIPA requirements for any trustee proposing to collect, use or disclose personal health information. Our office advised trustees in late 2003 and early 2004 that although there was no formal grace period in terms of enforcement of HIPA, we would be flexible in terms of requiring full compliance with HIPA. Nonetheless, we did say that any new programs should be expected to meet statutory requirements. Although the roll-out of the PPCC may have commenced prior to the proclamation of HIPA, the PPCC is a new program and must meet the HIPA requirements.

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[84] The letter from Saskatchewan Health dated July 30, 2003 advised among other things that "*on July 22, 2003, an Order-in-Council was signed by the Lieutenant Governor setting a proclamation date of September 1, 2003. . .*"

[85] HIPA received Royal Assent in 1999. It was amended in the spring of 2003 and then proclaimed in September 2003.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(ii) Organization

The Agency has appointed a Privacy Officer but did not do so until the spring of 2004 -- more than 7 months after the implementation of the PPCC started. HIPA does not explicitly require that a trustee appoint a Privacy Officer. In Canada however, we have more than 20 years experience with public sector privacy legislation. On the basis of that experience, the model that has evolved and proven most effective at providing operational leadership for privacy compliance is the appointment and tasking of a privacy officer within an organization.[86] This is reinforced by the accountability requirement in the Canadian Standards Association *Model Code for the Protection of Personal Information*[87] and the accountability requirement in the Saskatchewan government's *Overarching Personal Information Privacy Framework for Executive Government*[88].

I encourage the Agency to consider a dual appointment such that the Privacy Officer for purposes of HIPA is also the access and privacy coordinator (FOIP Coordinator) for purposes of *The Local Authority Freedom of Information and Protection of Privacy Act*. That ensures the full benefit of experience with both privacy laws and simplifies communication with our office.

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[86] Accountability Principle, *Canadian Standards Association Model Code for the Protection of Personal Information* CAN/CSA-Q830-96 [hereinafter "CSA Model Code"] / Ontario Information and Privacy Commissioner job description for FOIP Coordinator (available on-line: http://www.ipc.on.ca/scripts/index_.asp?action=31&N_ID=1&P_ID=11363&U_ID=9 and http://www.ipc.on.ca/scripts/index_.asp?action=31&N_ID=1&P_ID=14881&U_ID=0) / Annual Report of Saskatchewan OIPC (available on-line: http://www.oipc.sk.ca/Web%20Site%20Documents/2003%20--%202004%20Annual%20Report.pdf) Saskatchewan OIPC *"FOIP Folio"* article on FOIP Coordinator, January, 2004 (available on-line: http://www.oipc.sk.ca/Web%20Site%20Documents/FOIP%20FOLIO%20--%20January%202004.pdf)

[87] Ibid, Principle 4.1, 4.1.1 and 4.1.2

[88] *Overarching Personal Information Privacy Framework for Executive Government*. The Government of Saskatchewan, September 2, 2003, page 13 (available online: http://www.gov.sk.ca/newsrel/releases/2003/09/11-648-attachment.pdf) [hereinafter "Overarching"]

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(ii) Organization (cont'd)

In considering the structure of the office of Privacy Officer for the Agency, we have been referred to the following documents:

- Position Description for Position of Director, Cancer Registry.
- Draft Privacy Governance Model Discussion Paper (undated).
- Draft Privacy Oversight Committee Terms of Reference (June 2004).

The role of the Privacy Oversight Committee in the Agency is a feature we had to consider in assessing the 'organizational safeguards' required by section 16 of HIPA. The Privacy Officer's job description has her providing leadership to the Committee comprised of senior management representatives but she does not chair the Privacy Oversight Committee. In the experience of our office, there is often a natural tension between the typical role of a Privacy Officer and the core business focus of the senior management of an organization. This is the reason that, in public sector privacy legislation, there is usually an explicit requirement that the head of a public organization is accountable but can delegate responsibility to a FOIP Coordinator.[89] It has been found to be very important in the public sector that the FOIP Coordinator usually reports directly to the CEO, or someone reporting to the CEO, to ensure that access and privacy issues are not lost or overwhelmed in the mid or senior management of an organization. I recognize that HIPA does not include such an express vesting of responsibility in the CEO of a trustee. It follows then that it is important that a Privacy Officer in a trustee organization be expressly mandated by the CEO in a way that will ensure that privacy and access considerations can be communicated clearly and simply between the Privacy Officer and the CEO.

[89] LAFOIP, supra, note 8, section 50

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(ii) Organization (cont'd)

From the Agency's material that we have reviewed, it is not clear that the Privacy Officer is expressly mandated to report to the CEO of the Agency. It is not clear that the Privacy Oversight Committee is principally a resource to "assist" rather than to "direct" the Privacy Officer to achieve full compliance with HIPA and privacy 'best practices'. The Position Description for the Privacy Officer has her reporting to the Executive Director of Information Management. The same Executive Director chairs the Agency's Privacy Oversight Committee comprised of representatives from senior management.

That same Committee is mandated, among other things, to resolve all privacy complaints, to review and make recommendations for approval of any new privacy policies to ensure statutory compliance, to review individual privacy violations and to *"act as an enforcement body of all Agency privacy policies"*. This Committee reports to the Management Coordinating Committee.

I also note that in the job description there is a provision for the Privacy Officer to liaise with Saskatchewan Health and participate in provincial initiatives to ensure the security and privacy of personal health information and the adherence to applicable legislation for the collection and the use of the information. Saskatchewan Health is responsible for administration of HIPA but our office is responsible for oversight and enforcement of HIPA. I recommend that the job description should also mandate liaison with our office for purposes of HIPA compliance. This would correspond to the mandates of many Privacy Officers in other provinces with a stand-alone health information statute.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(iii) Policies and Procedures

HIPA does not particularize the kinds of safeguards required to discharge the section 16 obligation.

Our office views *Guidelines for the Protection of Health Information*[90] produced by Canada's Health Informatics Association as the relevant standard or best practice for Saskatchewan trustee organizations. In addition, there is much useful information in the Privacy and Security Rules published under the United States *Health Insurance Portability and Accountability Act of 1996.*[91]

Although earlier in this Report I distinguished the screening program from the cancer registry, I find that when it comes to consideration of the security of personal health information, the Standards for Cancer Registries produced by the North American Association of Central Cancer Registries, Inc. is a useful and relevant tool. In particular, I refer to the section on Standards section 2.2.7.1 to 2.2.8.1.[92]

To discharge its obligation under section 16 of HIPA, I find that a trustee must address three different kinds of safeguards: (1) administrative; (2) technical and (3) physical.

In addition to the contractual arrangements made with other trustees for purposes of PPCC or information management services provided by the Agency to the two large health regions, the Agency has also developed a number of safeguards to protect the personal health information under its control.

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90 *Guidelines for the Protection of Health Information.* Canada's Health Informatics Association, 2004 (available online www.coachorg.com)

91 *Health Insurance Portability and Accountability Act* of 1996 (available online at www.hhs.gov/ocr/hipaa/privrulepd.pdf)

92 Havener, L (Ed). *Standards for Cancer Registries Volume III: Standards for Completeness, Quality, Analysis, and Management of Data.* Springfield (IL): North American Association of Central Cancer Registries, Inc., October 2004, pages 18-19

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(iii) Policies and Procedures (cont'd)

I find that the Agency has met the section 23(2) requirement to restrict employee access on a 'need-to-know' basis through administrative safeguards, physical safeguards and technical safeguards.

(a) Administrative Safeguards

I have found appropriate protocols for the release of personal health information over the telephone. There is a process for gross checks to be undertaken to ensure no other clients with last name and address exist on database. The Agency advises that the release of information is carefully monitored to avoid inappropriate release.

I have reviewed a variety of forms and procedures that have been developed by the Agency for the release of health information by mail or by telephone. For the greatest part, these forms and procedures appear to be appropriate and in conformity with HIPA requirements.

There is some confusion in the forms utilized for purposes of access and disclosure. It would be useful to redesign the forms so there is a clear distinction between access (a right exercised by any individual) and disclosure (a discretionary decision of a trustee). In the exercise of one's right of access under section 12 there is entitlement to all personal health information subject only to sections 38 and the appropriate fees permitted by section 39. In the exercise of the discretion to disclose, the trustee is limited by sections 9, 10, 21, 23, 27, 28 and 29.

This should accommodate both a request for access by the individual and a request from any surrogate enabled by reason of section 56 of HIPA.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(iii) Policies and Procedures (cont'd)

(a) Administrative Safeguards (cont'd)

I find the Agency has met the requirements for administrative safeguards contemplated by section 16 of HIPA except for the need to create an access form separate from a consent to disclosure form.

As a condition of employment and/or for those who have access to patient/client information with the Saskatchewan Cancer Agency, employees, volunteers, contracted staff on special projects, and students are required to sign a Confidentiality Agreement

The Agency's Privacy Officer has the authority to conduct investigations and audits to ensure compliance with privacy policies.[93]

The Agency advises that the Prevention & Early Detection Division has very little staff turnover. Therefore, when hired, staff is trained one-on-one basis. Only staff requiring knowledge of and access to, client files in order to perform their job duties are trained in those specific areas.[94]Clearly, it is reasonable to expect that training of staff should reflect the size of the organization and its particular needs and core business. It is the responsibility of each trustee to determine how best to train its staff to HIPA compliance.

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[93] "the Package", supra, note 40, page 16
[94] Ibid, page 8

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(iii) Policies and Procedures (cont'd)

(a) Administrative Safeguards (cont'd)

As an oversight body however, we make the following observations:

- As we work to build a strong culture of privacy and confidentiality in and among all Saskatchewan trustees and trustee organizations, all staff of a trustee organization should receive HIPA training. The experience in other provinces with a health information law is that training should involve all employees, volunteers, contractors and students who work in or for a health trustee organization. The content and intensity of the training will reflect the particular roles and needs of different employee groups in an organization but all of those employees and others should have some basic understanding of privacy, confidentiality and HIPA.

- All staff should be required to take a confidentiality pledge but the value and impact of the pledge requires some additional information about privacy and confidentiality and HIPA to be meaningful. This would include information not just about the specific duties in HIPA for collection, use, disclosure, access and correction but also on all of the general duties imposed on any trustee and its staff. At the same time, it would be appropriate to provide some broader information on privacy and privacy regulation so that staff not only knows the rules but have some understanding of why they are important.

- The reported response to a number of Saskatchewan women concerned about the PPCC however, and some apparent confusion we encountered over the difference between 'privacy' and 'confidentiality', suggest that staff training should be a priority.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(iii) Policies and Procedures (cont'd)

(a) Administrative Safeguards (cont'd)

Record retention rules for PPCC records are dictated to some extent by contractual arrangements with the RQRHA and the SRHA. Hard copy records are transitory; electronic records are permanent. Copies of hard copy records are shredded after information is verified through data quality assurance processes. The original documents are retained at medical clinics and/or health region laboratories.[95]

The Agency has referred us to a number of written policies that it has adopted or which are awaiting approval and implementation:

- SCA, Appropriate Use of Information Technology Resources (Draft) – There is no policy number, nor issue date. We were informed by the Agency that this policy has not been approved by the SCA's Management Coordinating committee and is currently being revised.
- Prevention and Early Detection Policy Number 400, Policy Title: Protection of Client Privacy – effective January 1, 2004.
- Computer Security Standard for Cancer Screening Programs – effective January 7, 2004.
- SCA Policy Number HR 501, Policy Title: Confidentiality Agreement – issued March 7, 1992 and approved September 13, 2004.
- SCA, Information for Research and Statistics (Staff), Policy Number DS - 01 – effective date: May 15, 1996 and revised: November 1, 1990 - *The purpose of this policy is to regulate the manner in which information is released, taking into consideration the individual's right to privacy, the doctor-patient relationship, and the cost of providing such information.*

[95] Ibid, page 16

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(iii) Policies and Procedures (cont'd)

(a) Administrative Safeguards (cont'd)

- SCA, Information for Research and Statistics (Non-staff), Policy Number. DS-02 – effective date: May 15, 1986 and revised: November 1, 1990. – *The purpose of this policy is to regulate the manner in which information is released, taking into consideration the individual's right to privacy, the doctor-patient relationship, and the cost of providing such information.*
- Use and Disclosure within the care team and disclosure to family members – No copy has been provided to our office to review.
- Systems Service Contract #SCA 002, May 2002 between the Agency and Technology Management Corporation (TMC) – the majority of TMC's work in connection with the PPCC is now complete, but may continue to provide service (for example, with respect to providing software support and maintenance). In addition to the confidentiality provisions contained in the service agreement, the parties entered into a more general Data Access Agreement dated September 10, 2002 that includes a wide range of obligations to protect confidentiality of personal information that TMC may access in providing service to the Agency.

Agreement between Saskatchewan Health and Saskatchewan Cancer Agency

This agreement antedates HIPA but it formalizes the disclosure of registration information by Health to the Agency pursuant to the provisions of *The Freedom of Information and Protection of Privacy Act*. This includes Schedule A (health information to be released to the Cancer Agency), Schedule B (Cancer Agency information to be Released to Health), and Schedule C (health information to be Returned to the Cancer Agency). The agreement defines and limits the use that can be made of the information.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(iii) Policies and Procedures (cont'd)

(a) Administrative Safeguards (cont'd)

Although when HIPA came into force, the Agency had not achieved full compliance with section 16 of HIPA, I recognize that the Agency has been diligently working since that time to complete and implement the missing pieces. When I first met with Agency representatives more than one year ago, I was advised of the intention to hire a Privacy Officer and then to have that Privacy Officer lead a comprehensive review of the privacy policies of the Agency. As noted earlier, the Privacy Officer was designated in the spring of 2004. The Confidentiality Policy #HR 501 was approved by the Agency's senior management team on September 12, 2004. We have not seen any comprehensive review of the privacy policies but assume that is because the Agency was well aware of this review by our office.

On the basis of the allegations of women who complained to the Agency, there appears to be a need for greater clarity as to:

- the legal authority for the PPCC,
- the meaning of "privacy",
- the role of consent,
- an opt-out procedure and what it means,
- security procedures
- other disclosures of the information,
- the linkage with family physicians,
- and numerous other matters.

To address these matters may involve staff training, communication and information practices but it will also involve policy and procedures.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(iii) Policies and Procedures (cont'd)

(a) Administrative Safeguards (cont'd)

I understand from the Agency that some of the materials to address section 16 requirements of the Agency were intended to be created by the CIO Privacy Forum. I have had the opportunity to meet with this group on two occasions and recognize the value of this kind of collaborative experience. On the other hand, the responsibility in section 16 and indeed, throughout HIPA, is that of individual trustees. When HIPA went into force September 1, 2003, the Agency relied on the authority it had, by virtue of provisions such as section 27(2) of HIPA, to collect, use and disclose personal health information. The corresponding protection for Saskatchewan women founded in the general duties such as sections 9 and 16 was not installed at the same time. It became the clear responsibility of each trustee to ensure that it was putting in place the policies and procedures required by section 16 and to meet other general duties as quickly as possible. I do not believe that HIPA contemplates that the cervical health information of Saskatchewan women would be collected, used and disclosed without consent and without the knowledge of those women, in many cases, without the protection of the full range of mandatory safeguards. In other words, if the missing pieces were not being generated quickly enough through the Privacy Forum, it was the responsibility of each trustee to develop its own instruments.

(b) Physical Safeguards

I find the Agency has appropriate physical safeguards. This includes restricted access to the physical premises. The building is to be locked and alarm system activated after regular hours of operation. Access codes and key will be required to enter the building and access premises. Keys are assigned on an individual basis and are tracked to ensure return at the end of employment and/or contact.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(iii) Policies and Procedures (cont'd)

(b) Physical Safeguards (cont'd)

Access to Agency database is limited to:

- PPCC staff as outlined in the Data Sharing agreement;
- Regina Qu'Appelle and Saskatoon Regional Health Authority cytology and laboratory information systems personnel;
- Agency information Management Division personnel;
- Service contractor staff involved in PPCC software development and maintenance.

Role based access is limited to PPCC database to those who have legitimate need to know. By request, PPCC staff will provide Primary Care providers, and their staff, information about the Primary Care provider's own patients.[96]

To avoid inadvertent access and viewing of the two programs (PPCC and SPBC), workstations for the two programs are also located in physically separate areas.[97]

While all staff has access to SPBC due to the nature of the program and staff assignments, not all staff has access to PPCC. Therefore, physical client records pertaining to PPCC shall be stored in locked areas after regular hours of operation. Offices, within which PPCC activities are carried out, will be locked upon exit from the building. Servers and networking equipment are physically secured behind a locked door.[98]

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[96] Ibid, page 5
[97] Ibid, page 17
[98] Saskatchewan Cancer Agency, Computer Security Standards for Cancer Screening Programs, January 7, 2004

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(iii) Policies and Procedures (cont'd)

(b) Physical Safeguards (cont'd)

Paper records received and/or produced are to be shredded upon completion of use by staff. This would include letters, cytology reports, histology reports, colposcopy reports and all other information received relevant to a specified client of the PPCC. Records retained for the purposes of file completion, quality assurance, and/or patient follow-up are protected as noted above.

Given concerns we have heard from women where letters from the Agency were going to ex-spouses, adult children, strangers and former residences, we have considered whether there is better security that could be incorporated into the PPCC mail-out program. This would be particularly important when transmitting Pap test results to women. If the Agency decides not to use registered mail that would require a signature from the addressee, it should at least consider the use of double envelopes. The external envelope would give the general address and name. The internal envelope would be marked for opening only by a named individual. This would be a precaution against accidental access to the information by unauthorized persons.[99]

(c) Technical Safeguards

On October 19, 2004, our office met with the Agency's systems analyst responsible for technical security features relevant to the Program. We subsequently received a good deal of additional information on security features. The technical safeguards utilized by the Agency reflect industry best standards.

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[99] Guidelines in the European Union, supra, note 25, page 13

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(iii) Policies and Procedures (cont'd)

(c) Technical Safeguards (cont'd)

Some general features include the following:

- Firewalls.
- Encrypted transmissions with VPN technology.
- Use of private keys to decrypt files.
- Individualized passwords within an inquiry based system limited by user roles.
- Use of Oracle for backup systems.
- No access to the server allowed except for domain administrators.
- Data masks, and
- Built-in ability for process audits.

We choose not to detail those security features in this report to avoid compromising the security of the personal health information in the custody or under the control of the Agency. We have determined that there is currently an appropriately high level of security for the personal health information in the PPCC that is under the control of the Agency.

I find that the Agency has met the requirements for technical safeguards as required by section 16 of HIPA.

We have however identified two areas of concern:

(1) Although there is an audit capability of the information system employed for purposes of the Program there is no clear requirement for specific responsibility tasked to someone to undertake regular audits to ensure full compliance with the Agency policies and procedures. In our view, given the sensitivity of the personal health information in question, someone such as the Privacy Officer for the Agency should be charged with routinely surveying access patterns to ensure there is no unauthorized or inappropriate access to personal health information.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(iii) Policies and Procedures (cont'd)

(c) Technical Safeguards (cont'd)

(2) In addition, the Agency has two different screening programs utilizing the same hardware and software in the Agency's offices, i.e. the screening program for breast cancer and the cervical cancer screening program. Efforts have been made to avoid inadvertent access and viewing of the two programs by separating the workstations for the two programs in physically separate areas. A small number of senior employees have access to both screening programs. I question whether there are appropriate safeguards to protect against data matching of the two databases at some future date. I am particularly mindful of the very broad sweep of section 27(2) of HIPA and the prominence assigned by the Agency to "quality assurance" activities. I recommend that to address any concern over prospective 'function creep' the Agency commit to Saskatchewan women that it will not in the future data match unless it has first completed a Privacy Impact Assessment and provided that to our office for our review and comments.

(iv) Privacy Impact Assessment

I applaud the initiative of the Agency in undertaking a Privacy Impact Assessment in February, 2004. The Agency subsequently shared this document and its analysis with our office. The PIA was done at a time when there was virtually no interpretative material available in Saskatchewan to assist trustees achieve compliance with HIPA. In other words, the Agency was in the unenviable position of having to guess at how our office, and potentially, the courts in Saskatchewan will interpret the provisions of this complex law.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(iv) Privacy Impact Assessment (cont'd)

In the spring of 2004 our office published on our website, www.oipc.sk.ca a Saskatchewan specific PIA with an expectation that organizations would modify the form for their particular application. We have received feedback that this has been awkward and that statute specific PIAs would be more useful. Accordingly, we have since worked on a series of PIAs that are statute specific. We hope to publish our health information PIA in the spring of 2005. This may be helpful to the Agency when it undertakes PIA on future projects.

A privacy impact assessment however is most valuable if it is undertaken prior to the commencement of a program. For future programs, I would strongly encourage the Agency to undertake the PIA at an earlier stage. This would permit redesign of a project to accommodate specific privacy needs more easily than after the program is implemented.

In reviewing materials that the Agency considered in its PIA, it is interesting to note that the issue of opt-out for women receives relatively little attention as does the question of a woman's constitutional right to determine who should get access to her cervical information and for what purpose. The various articles in medical journals, national strategy reports and comparative analyses of screening programs focus on the medical and scientific issues involved with the diagnosis of cervical cancer.

There is reference in the scientific/medical literature referenced in the completed PIA to the importance of ensuring that cervical screening is "*confidence building for the client while being practical for the health service provider to deliver*".[100]

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[100] *Building on Success: A Pan-Canadian Forum on Cervical Screening*, Report of Proceedings. Ottawa, November 21-22, 2003. page 86

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(iv) Privacy Impact Assessment (cont'd)

I note that among the four provinces with a health information protection law, only Alberta specifically prescribes the use of PIAs. In that province's *Health Information Act*, a custodian (roughly equivalent to a Saskatchewan "trustee") must prepare a PIA that "*describes how proposed administrative practices and information systems relating to the collection, use and disclosure of individually identifying health information may affect the privacy of the individual who is the subject of the information.*"[101] The custodian must submit the privacy impact assessment to the Commissioner for review and comment before implementing the new proposed practice or system.

In the other provinces, there appears to be a practice of trustees preparing PIAs and seeking feedback and comments from the Information and Privacy Commissioner.

I strongly encourage institutional trustees in Saskatchewan who may be contemplating a new initiative that will significantly impact privacy to complete a PIA and submit it to our office for review and comments. This may be the most effective and time efficient way to minimize the number of breach of privacy complaints and reviews under HIPA.

(v) Transparency

The steps required of a trustee under section 9 of HIPA should be proportionate to the sensitivity of the personal health information in question. In other words, the more sensitive the information, the greater the efforts required by a trustee to communicate its policies and procedures to individuals. In this case, the foundation of the PPCC is the collection of Pap test results. What is being measured is abnormalities that may suggest the possibility of cervical cancer. I view this as particularly sensitive personal health information. I find that when the personal health information is particularly sensitive, such as cervical health information, the threshold for transparency should be a higher standard.

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[101] *Health Information Act*, RSA 2000, c.H-5, section 64 [hereinafter "HIA"]

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(v) Transparency (cont'd)

The Agency has not sent a letter or pamphlet to every eligible woman in Saskatchewan explaining the PPCC, including the rationale and statutory authority for the program, how each woman's personal health information will be collected, used and disclosed, the new role of the Agency in engaging in direct communication with women about their test results and whether a woman can or cannot opt out of the PPCC.[102] If it had done so, there would likely be no issue as to whether the Agency has met the transparency requirement.

I have no doubt that the Agency has made a serious effort to communicate with Saskatchewan women through electronic and print media starting in 2003. This effort, however, was inadequate given:

- the sensitivity of the information in question,
- the fact registration has been compulsory and
- the fact that disclosure of laboratory results to the Agency and its direct communication with women would not have reasonably have been expected by all eligible Saskatchewan women.

When such a large body of women is involved with the PPCC, the Internet provides a relatively simple, inexpensive way to provide information to many about the PPCC. The website of the Agency (www.scf.sk.ca/default.htm) does not disclose a comprehensive privacy and confidentiality policy, nor does it disclose how that information can be accessed. It does not provide contact information for the Privacy Officer of the Agency. It does not indicate the specific statutory authority for the PPCC, nor what steps are available to a woman who wishes to opt-out of the PPCC. There is no reference to the statutory right to submit a complaint or to request a review of a decision of the Agency by our office.

[102] The Alberta Cancer Board sent a letter to every eligible woman in that province about its cervical cancer screening program at the time it was rolled-out.

XVI GENERAL DUTIES OF A TRUSTEE (CONT'D)

4. Saskatchewan Cancer Agency (cont'd)

(v) Transparency (cont'd)

I recognize that the Agency has provided information to Saskatchewan physicians about the PPCC. The experience of our office, however, is that this has not resulted in appropriate communication about the PPCC to all affected women.

We have reviewed the following pamphlets produced by the Agency:

- Cervical Screening -- The Program
- Your Pap Test Result -- What Does It Mean?
- Cervical Screening – In Your Hands
- Protecting Your Privacy – What We Do

I find that these brochures are attractive, accessible and informative. They refer to the role of "your health care provider". Someone who learns of an abnormal Pap test result is encouraged to make an appointment with their health care provider. Also, women are encouraged *"For your best health practice, discuss these factors with your health care provider to determine your individual risk, and develop a Pap test schedule."*[103] The printed materials available to women were in our view deficient. Missing features include:

- No clear indication of the authority for the collection, use and disclosure of this information
- No reference to oversight provided by our office and the statutory right to complain to our office under HIPA
- No contact information for our office.

I find that the Saskatchewan Cancer Agency has failed to discharge its duty under section 9 of HIPA in that it has failed to ensure all Saskatchewan women are informed about the anticipated uses and disclosures of their cervical health information for purposes of the PPCC.

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[103] Cervical Screening, supra, note 30

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE

A. Specific Duties

There are a number of different trustee activities that are engaged in this investigation. This includes collection, use, disclosure and access to personal health information. Prior to examining the specific transactions involved with the cervical cancer screening programs it is appropriate to identify the rules that govern those four different activities.

B. Collection

Part III of HIPA

19 In collecting personal health information, a trustee must take reasonable steps to ensure that the information is accurate and complete.

20(1) Where one trustee discloses personal health information to another trustee, the information may become a part of the records of the trustee to whom it is disclosed, while remaining part of the records of the trustee that makes the disclosure.

(2) Where personal health information disclosed by one trustee becomes a part of the records of the trustee to whom the information is disclosed, the trustee to whom the information is disclosed is subject to the same duties with respect to that information as the trustee that discloses the information.

Part IV of HIPA

23(1) A trustee shall collect, use or disclose only the personal health information that is reasonably necessary for the purpose for which it is being collected, used or disclosed.
(2) A trustee must establish policies and procedures to restrict access by the trustee's employees to an individual's personal health information that is not required by the employee to carry out the purpose for which the information was collected or to carry out a purpose authorized pursuant to this Act.

24(1) A trustee shall ensure that the primary purpose for collecting personal health information is for the purposes of a program, activity or service of the trustee that can reasonably be expect to benefit the subject individual.

(2) A trustee may collect personal health information for a secondary purpose if the secondary purpose is consistent with any of the purposes for which personal health information may be disclosed pursuant to section 27, 28 or 29.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

B. Collection (cont'd)

Part IV of HIPA (cont'd)

> *24(3) Nothing in this Act prohibits the collection of personal health information where that collection is authorized by another Act or by a regulation made pursuant to another Act.*
>
> *(4) A trustee may collect personal health information for any purpose with the consent of the subject individual.*

> *25(1) Subject to subsection (2), a trustee shall collect personal health information directly from the subject individual, except where:*
>
> . . .
>
> *(2) Where the collection is for the purpose of assembling the family health history of an individual, a trustee may collect personal health information from the individual about other members of the individual's family.*
>
> *(3) Where a trustee collects personal health information from anyone other than the subject individual, the trustee must take reasonable steps to verify the accuracy of the information.*

1. Saskatchewan Physicians

Saskatchewan family physicians collect the Pap specimens from female patients in their clinics across Saskatchewan. We have received no complaints that physicians have collected the accompanying personal health information improperly. I find that this information would be for the primary purpose of diagnosing, treating, and caring for female patients and therefore there is compliance with section 24(1). In addition, I find there would be implied consent that meets the requirements of section 6. The implied consent would be for the purpose of diagnosis, treatment and care of the patient by the family physician. I am not satisfied that many Saskatchewan women have even turned their mind to the ultimate disclosure of their personal health information by the laboratories in the two largest regional health centres to the Agency, let alone consented at this point to the further future disclosure of this information by the Agency.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

B. Collection (cont'd)

1. Saskatchewan Physicians (cont'd)

I find that the personal health information generally collected by family physicians as part of the Pap test process and then disclosed to the regional health authority laboratories is reasonably necessary for the purpose of collection and meets the requirements of section 23(1). I further find that it would not be practicable to disclose only de-identified personal health information since that would not serve the purpose of the diagnosis, treatment and care of the woman patient.

The physician collects the personal health information directly from the woman in accordance with section 25(1)(a) and I find there would be implied consent at the point of collection.

2. Saskatchewan Health

The relevant type of personal health information that is collected by Saskatchewan Health is chiefly registration information. That is defined in HIPA as follows:

> *"2 In this Act:*
>
> . . .
>
> *(q) "registration information" means information about an individual that is collected for the purpose of registering the individual for the provision of health services, and includes the individual's health services number and any other number assigned to the individual as part of a system of unique identifying numbers that is prescribed in the regulations;"*

The department collects information from individuals pursuant to *The Department of Health Act* [104] when they make application to be registered in the Saskatchewan health services plan. The application form is a two page document that collects identity information such as name, birth date, sex, Social Insurance Number and Indian Status Registry Number, mailing address, occupation, employer contact information, citizenship status and anticipated residency details.

[104] *The Department of Health Act*, R.S.S. c.D-17

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

B. Collection (cont'd)

2. Saskatchewan Health (cont'd)

There is an on-line application form and additional information on the Saskatchewan Health website but I can find no information on that website that mentions the PPCC. Given the automatic process for enrolment of some 300,000 Saskatchewan women in the PPCC and the inability of those women to opt-out, it is particularly important that they be provided with adequate information. Even where there is no consent, there must be a reasonable degree of transparency.

Saskatchewan Health should in some fashion ensure that women registering for health insurance coverage are informed that their personal health information will be shared with the Agency for purposes of the PPCC in accordance with section 9(1) and (2) of HIPA. For women already registered, Saskatchewan Health should forthwith advise them of the data sharing arrangement with the Agency for purposes of the PPCC. The department website should contain clear information on its role in supporting the PPCC and what is done with the personal health information of Saskatchewan women.

It is important that Saskatchewan Health meets its obligation in section 19 by taking *"reasonable steps to ensure that the information is accurate and complete"*. We have heard from a number of women who have received notification letters from the Agency that were misaddressed. We understand that the PPCC obtains registration information from Saskatchewan Health as well as the health regions for purposes of the PPCC database. Addresses are not required by the regions although if they are collected, they will be sent to the Agency. The PRS would over ride any addresses from the regions. The Department asserts that it is the responsibility of Saskatchewan women to provide Saskatchewan Health with information on changes of address, marital status, etc. I am not sure that all Saskatchewan women will have clearly understood that failure to update their address or registration information with the Department would result in a letter with their Pap test results going to a parent, an ex-spouse or some wrong address. Given the sensitivity of the information in those letters from the Agency, there is a shared responsibility among the Department, the health regions and the Agency to meet the section 19 duty.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE

B. Collection (cont'd)

3. Health Regions

The two health regions collect the specimens and additional personal health information when they receive both from family physicians throughout the province. These collection practices appear to conform to sections 23(1), 24(1) and in addition there would be implied consent for this collection pursuant to section 24(4) and section 6(4). The collection by the two health regions is indirect but is authorized by section 25(1)(f) and what we take to be implied consent pursuant to section 25(1)(a).

Women would likely recognize that laboratory work on the Pap specimen would require analysis by a proper laboratory in order that their family physician would acquire the lab results for purposes of diagnosis, treatment and care.

4. Saskatchewan Cancer Agency

The Agency relies on sections 24, 25 and 26 and specifically asserts that the primary purpose for collection is for a program that can reasonably be expected to benefit the subject individual. The Agency also asserts that its indirect collection of the personal health information of these Saskatchewan women is supported by section 27.

This personal health information is in the custody and control of the Agency. In the result, HIPA applies to the information collected, used and disclosed in the course of the operation of the cervical cancer screening program.

Certain kinds of personal health information have been carved out from Parts II, IV and V of HIPA.[105] These cover the following areas:

Part II -- Rights of the Individual
Part IV -- Limits on Collection, Use and Disclosure of Personal Health Information by Trustees
Part V -- Access of Individuals to Personal Health Information

[105] HIPA, supra, note 1, s. 4(4)

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

B. Collection (cont'd)

4. Saskatchewan Cancer Agency (cont'd)

The above noted three Parts of HIPA do not apply to personal health information obtained for purposes of section 16 of *The Cancer Foundation Act*.[106] This would relate to collection of personal health information. Some of the women who have complained to our office were apparently advised by the Agency that the legal basis for the collection of the information by the Agency was section 16 of *The Cancer Foundation Act*.

That statutory provision is as follows:

> *16(1) Any physician or dentist who examines, diagnoses, or treats a patient, or the operator of any hospital in which a patient is examined, diagnosed or treated, shall furnish to an official of the foundation any information with respect to that examination, diagnosis or treatment that the official may request.*
>
> *(2) No action or other proceeding for damages lies against any physician, dentist or operator of a hospital in respect of the furnishing to the foundation of any information or report with respect to any case of cancer examined, diagnosed or treated, by that physician or dentist, or at that hospital.*

The focus and effect of section 4(c) of HIPA is on the sharing of personal information by a primary care provider or hospital operator to an official of the Agency. It protects that primary care provider or hospital operator from complaints and enforcement action. It does not relieve the Agency from doing the right thing with that information.

I should note that section 16 of *The Cancer Foundation Act* was not raised in our discussions with the Agency as authority for this Program. It clearly was mentioned to at least some of the women who called the Agency and regional health authorities to complain about the PPCC. I find that section 16 does not apply here. I have seen no evidence of the request from the Agency contemplated by section 16 to a physician or dentist. More importantly, *The Cancer Foundation Act* deals with information about someone who has been diagnosed with cancer.

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[106] Ibid, s. 4(4)(c)

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

B. Collection (cont'd)

4. Saskatchewan Cancer Agency (cont'd)

The vast majority of women affected by the PPCC do not meet that criterion.

The Agency collects the personal health information indirectly and presumably pursuant to section 25(1)(f) since this is a result of a disclosure from another trustee namely, the two largest health regions.

No issue has been raised with our office as to the accuracy of the information collected by the Agency. Section 25(3) is not engaged on the facts of this investigation.

C. Use

Use involves the handling or treatment of personal health information within a single trustee organization.

None of the complaints to our office raise issues with the use by family physicians, by Saskatchewan Health, or by the regional health authorities. The only use that appears to be in issue is that of the Agency.

Section 26 governs use by a trustee. A trustee shall not use personal health information in the custody or control of the trustee except with the consent of the subject individual or in accordance with this section. A trustee may use personal health information:

> *26(2)(a) for a purpose for which the information may be disclosed by the trustee pursuant to section 27, 28 or 29;*
>
> . . .
>
> *(c) for a purpose that will primarily benefit the subject individual; or*
>
> *(d) for a prescribed purpose.*

XVII Relevant Specific Duties of a Trustee (cont'd)

C. Use (cont'd)

The Agency has asserted that it is authorized to collect the personal health information in question by section 26(2) in that the purpose for collecting the information is a purpose that will primarily benefit the subject individual. This would be a use for a purpose for which the data may be disclosed pursuant to sections 27 and 28 and it is submitted by the Agency that section 26(2)(a) also applies.

The benefit contemplated by section 26(2)(c) must primarily benefit the specific woman. This provision would not apply if the primary benefit was for the PPCC or indeed the operations of the Agency or any of its partners.

On this question, I have had the benefit of extensive discussion with the Medical Advisor to the PPCC. That medical professional advises that, in her opinion, the PPCC does provide a benefit to each individual woman who is automatically enrolled in the PPCC. That benefit will be discussed in detail later in the analysis of the "disclosure" under the PPCC.

When this office reviews the discretionary decisions of medical professionals under HIPA, the standard we will use is whether the discretion was exercised according to the objects and purposes of the legislation and that it has not been exercised for an improper or irrelevant purpose.

1. Quality Assurance

There is no definition of "quality assurance" in HIPA. Since quality assurance has been relied upon by the Agency as part of the justification for the collection, use and disclosure activities of the PPCC, it will be important to distinguish between quality assurance for the benefit of a specific patient and quality assurance for the benefit of a class or group of people. If the latter, section 26(2)(c) would not apply.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

C. Use (cont'd)

1. Quality Assurance (cont'd)

Section 27(4)(g) of HIPA permits a trustee to disclose without consent to a "quality of care committee" established by one or more trustees to study or evaluate health services practice in a health services facility, health region or other health service area that is the responsibility of the trustee, if the committee (i) uses the information only for the purpose for which it was disclosed; (ii) does not make a further disclosure of the information; and (iii) takes reasonable steps to preserve the confidentiality of the information. I find that the intention of the Assembly was that personal health information can be used and disclosed for quality of care purposes without consent but only if the elements of that subsection can be met or if authority can be found elsewhere. Otherwise, the only quality of care purpose that would be permitted without consent would be quality assurance that benefited a specific patient in a differential fashion. In the result, a quality assurance purpose would not justify use or disclosure without consent unless all of the elements of section 27(4)(g) are present.

Given my interpretation of section 26(2)(a), 27(4)(g) and 27(2)(b) should be read so that they would not authorize uses without consent for the purpose of quality assurance activities that do not differentially benefit the individual.

2. Health Research

Section 29 is also listed as a purpose for which personal health information can be used without consent. Section 29 sets out rules for the use and disclosure of personal health information for health research.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

C. Use (cont'd)

2. Health Research (cont'd)

Is the PPCC also health research? I ask this question since research is a significant component of the Agency's mandate.[107] I am mindful that collecting all of the information on the cervical health of 300,000 Saskatchewan women and related health history would clearly offer some important research possibilities. There is no definition of "health research" in HIPA. I adopt as a definition the following:

> *"Health research is the systematic investigation designed to develop or establish principles, facts or generalizable knowledge."*[108]

I am not clear on how one can clearly determine when health research ends and quality assurance activities begin.

As noted above, the PPCC is a health surveillance program. In the relevant literature, surveillance programs have been considered as closely aligned with research if they are not "research" proper.

> *"Are public health investigations "research"? Some are meant to generate generalisable knowledge and clearly are research. But some are real-time operational tools and they may affect subjects and their relations directly, which database research seldom does. Consent may or may not be sought; data are held in medical confidentiality, and public health organisations tend to be disciplined about this. But as experience accrues across cases, it may suggest hypotheses, shade over into research, and lead to the confirmation of generalisable knowledge. Many databases, such as many disease, drug, vaccine, device and transplant registries, and administrative databases, are used for medical care, and for public health studies, and for research."*[109]

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[107] Final Report, supra, note 2, page 18

[108] Canadian Institutes of Health Research. *"Guidelines for Protecting Privacy and Confidentiality in the Design, Conduct and Evaluation of Health Research: Best Practices Consultation Draft"*, Ottawa, April 2004, page 67

[109] Learning from Experience, supra, note 55, page 10

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

C. Use (cont'd)

2. Health Research (cont'd)

When the PPCC undertakes research then there are some special considerations that would apply[110]. This would be true whether the Agency undertakes research on personal health information already in its control or custody or whether it discloses to a different entity for that purpose.

If the trustee proposes to use personal health information or to disclose it for health research purposes, there is a requirement to obtain the express consent of the individual.[111] Consent may not be required if it is "not reasonably practicable" to obtain. To dispense with consent the following seven criteria must be satisfied:

(1) Research purposes cannot reasonably be accomplished using de-identified personal health information;
(2) Reasonable steps are taken to protect the privacy of the individual by removing all personal health information not required for the research;
(3) A designated research ethics committee determines that the potential benefits of the research project clearly outweigh the potential risk to privacy;
(4) In opinion of the trustee, the research project is not contrary to the public interest;
(5) Recipient must ensure information will be used only for the purpose set out in the agreement governing the research project;
(6) The agreement governing the project must require the recipient to ensure the information will only be used for the identified purpose; and
(7) The agreement governing the project must require the recipient to take reasonable steps to ensure the security and confidentiality of the information.[112]

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110 "HIPA", supra, note 1, section 29 (sets out a separate set of requirements for collection, use and disclosure.)
111 Ibid, section 29(1)
112 Ibid, section 29(2) refers to criteria numbers 1-4; Ibid, section 29(1)(c) refers to criteria numbers 5-7

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

C. Use (cont'd)

2. Health Research (cont'd)

In response to the difficulty of distinguishing "quality assurance" from "health research" an interesting initiative has been launched in Alberta. This initiative is examining the regulation of activities related to research but which would not be subject to a Research Ethics Board review.

> *"More recently, in Canada and elsewhere, the evolving need to strike an appropriate balance between protecting people and increasing knowledge has become more complex, as knowledge-generating activities in the health system have become widespread in a variety of forms intended to improve the planning and management of health services for the benefit of the public. While not usually defined as research, quality improvement, program evaluation and administrative data analysis are seen as necessary activities for managing the health system.*
>
> *At the same time, the distinction between such activities and research as it has traditionally been understood has been challenged with the growth of research activities that occur within, and change, health services themselves, such as health services research, collaborative projects involving both health services organizations and universities, and system-based policy research. Concurrently, there has also been growing sophistication and prevalence of management strategies that resemble or draw on research methodologies.*
>
> *While the relationships among all these knowledge-generating activities are not well defined, there is a sense that they exist along a continuum, and if ethical considerations apply at the research end of the continuum, ethical implications extend along the continuum to other forms of knowledge generating activity as well. The need for clarity regarding both the relationships and their ethical implications has become more urgent as legislation across Canada designed to ensure the protection and security of personal health information has focused special attention on activities understood to be research. For certain projects, this creates a pressing question: are they research projects, and hence, subject to legislation, or are they non-research projects, and hence, not subject to the legislation?"*[113]

I find that the use of personal health information by the Agency conforms with section 26(2)(a) of HIPA.

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[113] *Protecting People While Increasing knowledge: recommendations for a Province-wide Approach to Ethics Review of Knowledge-generating Projects (Research, Program Evaluation, and Quality Improvements) in Health Care* (Draft 2). Alberta Research Ethics Community Consensus Initiative, November 30, 2004.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

D. Disclosure

A disclosure of personal health information means the conveyance of personal health information by one trustee to either another trustee or some third party organization. I might summarize the disclosure rules in HIPA by organizing them in three different categories:

1. Express Consent of the Individual

Personal health information can be disclosed with the consent of the individual[114]. This consent must meet the requirements in section 6.

The consent provision is as follows:

> *27(1) A trustee shall not disclose personal health information in the custody or control of the trustee except with the consent of the subject individual or in accordance with this section, section 28 or section 29.*

2. Core Business of the Trustee

There are two circumstances when consent will not be required for disclosure:

- If it is being disclosed for what would effectively be the core business of a trustee or for a consistent purpose.

- If it is being disclosed in order to provide care to an individual.

  This is sometime referred to as the "circle of care". I choose not to use that term since it is not mentioned or defined in HIPA and since we find there is no clear definition in current use in Saskatchewan. A similar term is utilized in the Pan-Canadian Framework although it appears to mean something different. Industry Canada and Health Canada refer to "circle of care" but that appears to represent something narrower than the intention in Saskatchewan and appears not to permit the widespread sharing of personal health information contemplated by Saskatchewan Health.

[114] HIPA, supra, note 1, section 5

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

D. Disclosure (cont'd)

2. Core Business of the Trustee (cont'd)

There is an important qualification before a trustee can rely on this authority for disclosure. If the trustee is a health professional, the disclosure must be *"in accordance with the ethical practices of the trustee's profession."*[115] If the trustee is not a health professional, then it must have established policies and procedures to restrict disclosure to those who require the information for carrying out the purpose for which the information was collected or to carry out a purpose authorized by the Act.

The specific provision is as follows:

> *27(2) A subject individual is deemed to consent to the disclosure of personal health information:*
>
> *(a) for the purpose for which the information was collected by the trustee or for a purpose that is consistent with that purpose;*
>
> *(b) for the purpose of arranging, assessing the need for, providing, continuing, or supporting the provision of, a service requested or required by the subject individual; or*
>
> *(c) to the subject individual's next of kin or someone with whom the subject individual has a close personal relationship if:*
>
> *(i) the disclosure relates to health services currently being provided to the subject individual; and*
>
> *(ii) the subject individual has not expressed a contrary intention to a disclosure of that type.*
>
> *(3) A trustee shall not disclose personal health information on the basis of a consent pursuant to subjection (2) unless:*
>
> *(a) in the case of a trustee other than a health professional, the trustee has established policies and procedures to restrict the disclosure of personal health to those persons who require the information to carry out a purpose for which the information was collected or to carry out a purpose authorized pursuant to this Act; or*
>
> *(b) in the case of a trustee who is a health professional, the trustee makes the disclosure in accordance with the ethical practices of the trustee's profession.*

[115] Ibid, section 27(3)(6)

XVII Relevant Specific Duties of a Trustee (cont'd)

D. Disclosure (cont'd)

3. Specified Exceptions to Consent Requirement

HIPA enumerates sixteen circumstances in which a trustee can disclose personal health information without consent. A trustee is not required to disclose but is authorized to exercise its discretion to disclose in any of those circumstances. In exercising oversight, our office does not substitute our discretion for that of a trustee but will determine if there is a reasonable basis for the exercise of the discretion and ensure that the discretion is not exercised for an improper reason.

27(4) *A trustee may disclose personal health information in the custody or control of the trustee without the consent of the subject individual in the following cases:*

(a) where the trustee believes, on reasonable grounds, that the disclosure will avoid or minimize a danger to the health or safety of any person;

(b) where, in the opinion of the trustee, disclosure is necessary for monitoring, preventing or revealing fraudulent, abusive or dangerous use of publicly funded health services;

(c) where the disclosure is being made to a trustee that is the successor of the trustee that has custody or control of the information, if the trustee makes a reasonable attempt to inform the subject individuals of the disclosure;

(d) to a person who, pursuant to The Health Care Directives and Substitute Health Care Decision Makers Act, is entitled to make a health care decision, as defined in that Act, on behalf of the subject individual, where the personal health information is required to make a health care decision with respect to that individual;

(e) if the subject individual is deceased:

(i) where the disclosure is being made to the personal representative of the subject individual for a purpose related to the administration of the subject individual's estate; or;

(ii) where the information relates to circumstances surrounding the death of the subject individual or services recently received by the subject individual, and the disclosure:

XVII Relevant Specific Duties of a Trustee (cont'd)

D. Disclosure (cont'd)

3. Specified Exceptions to Consent Requirement (cont'd)

(A) is made to a member of the subject individual's immediate family or to anyone else with whom the subject individual had a close personal relationship; and

(B) is made in accordance with established policies and procedures of the trustee, or where the trustee is a health professional, made in accordance with the ethical practices of that profession;

(f) where the disclosure is being made in accordance with section 22 to another trustee or an information management service provider that is a designated archive;

(g) where the disclosure is being made to a standards or quality of care committee established by one or more trustees to study or evaluate health services practice in a health services facility, health region or other health service area that is the responsibility of the trustee, if the committee:

(i) uses the information only for the purpose for which it was disclosed;

(ii) does not make a further disclosure of the information; and

(iii) takes reasonable steps to preserve the confidentiality of the information;

(h) subject to subsection (5), where the disclosure is being made to a health professional body or a prescribed professional body that requires the information for the purposes of carrying out its duties pursuant to an Act with respect to regulating the profession;

(i) where the disclosure is being made for the purpose of commencing or conducting a proceeding before a court or tribunal or for the purpose of complying with:

(i) an order or demand made or subpoena or warrant issued by a court, person or body that has the authority to compel the production of information; or

(ii) rules of court that relate to the production of information;

(j) subject to subsection (6), where the disclosure is being made for the provision of health or social services to the subject individual, if, in the opinion of the trustee, disclosure of the personal health information will clearly benefit the health or well-being of the subject individual, but only where it is not reasonably practicable to obtain consent;

XVII Relevant Specific Duties of a Trustee (cont'd)

D. Disclosure (cont'd)

3. Specified Exceptions to Consent Requirement (cont'd)

(k) where the disclosure is being made for the purpose of:

(i) obtaining payment for the provision of services to the subject individual; or

(ii) planning, delivering, evaluating or monitoring a program of the trustee;

(l) where the disclosure is permitted pursuant to any Act or regulation;

(m) where the disclosure is being made to the trustee's legal counsel for the purpose of providing legal services to the trustee.in the case of a trustee who controls the operation of a pharmacy as defined in The Pharmacy Act, 1996, a physician, a dentist or the minister, where the disclosure is being made pursuant to a program to monitor the use of drugs that is authorized by a bylaw made pursuant to The Medical Profession Act, 1981 and approved by the minister;

(n) in the case of a trustee who controls the operation of a pharmacy as defined in The Pharmacy Act, 1996 where the disclosure is being made pursuant to a program to monitor the use of drugs that is authorized by a bylaw made pursuant to The Pharmacy Act, 1996 and approved by the minister;

(o) in prescribed circumstances.

(5) For the purposes of clause (4)(h), where the personal health information in question is about a member of the profession regulated by the health professional body or prescribed professional body, disclosure may be made only:

(a) in accordance with clause (4)(i);

(b) with the express consent of the subject individual; or

(c) if the trustee has reasonable grounds to believe that the personal health information is relevant to the ability of the subject individual to practise his or her profession, on the request of the health professional body or prescribed professional body.

(6) Disclosure of personal health information pursuant to clause (4)(j) may be made only where the person to whom the information is to be disclosed agrees:

(a) to use the information only for the purpose for which it is being disclosed; and

(b) not to make a further disclosure of the information in the course of carrying out any of the activities mentioned in that clause.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

D. Disclosure (cont'd)

3. Specified Exceptions to Consent Requirement (cont'd)

Of the three categories in section 27 for disclosure, the one category that represents a substantial departure from the common law approach to patient autonomy is the deemed consent provision in section 27(2). Let us be clear that deemed consent is no consent at all.

E. Disclosure by Family Physicians to the Health Regions

Disclosure of personal health information by physicians to the health regions is for the purpose of diagnosis, treatment and care. It appears that there would be implied consent by Saskatchewan women for their family physicians to send their Pap test specimens to the laboratories operated by the regions for the purpose of analysis.

F. Disclosure by Saskatchewan Health to the Agency

The Agency has asserted that:

> *". . . It is reasonable to conclude that such disclosure is permitted by section 28 because Saskatchewan Health is disclosing registration information to a trustee for the purposes of that trustee providing health services. Thus, the collection and use of the data by the SCF in connection with the PPCC is permissible pursuant to sections 25 and 26."*[116]

The Agency assumed that the PRS data provided by Saskatchewan Health falls within the definition of registration information in section 2(q) and section 28(1)(a).[117]

The disclosure of registration information by Saskatchewan Health to the Agency cannot be brought within section 28 (3) in that it is disclosed to another trustee, namely the Agency and not to a regional health authority or affiliate. The only part of section 28(1) that could apply would be (a). Clearly this is a disclosure by the Minister of Health to a trustee but is it in connection with the provision of health services by the trustee?

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[116] Letter from MacPherson, Leslie & Tyerman, dated January 30, 2004, page 5
[117] Ibid, page 10

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

F. Disclosure by Saskatchewan Health to the Agency (cont'd)

"Health service" is not defined but I take this to refer to a service that directly benefits an individual as opposed to a service that benefits the management of a health region or the operations of another trustee.

I find that the disclosure of personal health information namely registration information from the Person Registry System by Saskatchewan Health to the Agency conforms with section 28(1)(a) of HIPA. The Medical Advisor of the PPCC advises that the PPCC does provide a health service to each of the women automatically enrolled in the PPCC. The nature of that service will be described in detail later in this Report.

We have reviewed an agreement on March 12, 2003, between the Agency and Saskatchewan Health regarding the disclosure of information from the Person Registry System to the Agency for purposes of the Screening Program for Breast Cancer and the Prevention Program for Cervical Cancer. We have also reviewed a document describing the security strategy for transfer of data from the Person Registry System and Vital Statistics databases in Saskatchewan Health to the Agency.

1. Disclosure from the Person Registry System (PRS)

The Freedom of Information and Protection of Privacy Act

The original disclosure from the Person Registry System antedates the proclamation of HIPA and therefore, according to Saskatchewan Health, was subject to *The Freedom of Information and Protection of Privacy Act* (FOIP Act).

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

F. Disclosure by Saskatchewan Health to the Agency (cont'd)

1. Disclosure from the Person Registry System (PRS) (cont'd)

The Freedom of Information and Protection of Privacy Act

According to Saskatchewan Health, authority for the disclosure exists in section 29(2)(h) of the FOIP Act and section 16 of the regulations:

> *"29(2)(h)(v) allows for a government institution to disclose information pursuant to an agreement or arrangement between the government and a local authority. The Saskatchewan Cancer Agency (or more properly the "Saskatchewan Cancer Foundation") is a local authority within the meaning of The Local Authority Freedom of Information and Protection of Privacy Act. Part II of the Appendix.*
>
> *16(c) of the Regulations allows for a disclosure "where the disclosure may reasonably be expected to assist in the provision of services for the benefit of the individual to whom the information relates . . .*
>
> *16(a)(iii) of the regulations provide for the disclosure to a local authority for the purpose of "verifying the accuracy of personal information held by the...local authority"*[118].

[118] Letter from Privacy Officer, supra, note 50, pages 2 and 3

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

F. Disclosure by Saskatchewan Health to the Agency (cont'd)

1. Disclosure from the Person Registry System (PRS) (cont'd)

Health Information Protection Act

According to Saskatchewan Health:

> *"As of September 1, 2003, The Health Information Protection Act applied to the disclosure. Authority for the disclosure in HIPA exists in at least two locations:*
>
> - *Clause 28(1)(a) provides for a disclosure by the Minister of Health to a trustee in support of health services. Specifically, 28(1)(a) reads:*
>
> *28(1) The minister may disclose registration information without the consent of the subject individual:*
>
> *(a) to a trustee in connection with the provision of health services by the trustee;*
>
> *All of the information provided from Health to the Agency from the PRS is "registration information" within the meaning of HIPA. Section 28(1)(a) of HIPA is consistent with the authorization to disclose found in section 16(c) of the FOIP regulations, that is, for the purpose of enabling health services to be provided by a trustee- the Cancer Agency- to the individuals to whom the information relates. (See discussion re. 16(c) of the FOIP Regulations above.)*
>
> *As you know, Saskatchewan Health is developing regulations that replicate much of section 28 in HIPA for the Cancer Agency. As we have discussed in the past, the intent is to ensure that the law places the Cancer Agency on an equal footing with Regional Health Authorities and affiliates in regard to the sharing of registration information. Such a regulation could also apply to the disclosures under discussion.*[119]"

[119] Ibid, page 4

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

F. Disclosure by Saskatchewan Health to the Agency (cont'd)

2. Disclosure from the Vital Statistics database

Authority for Vital Statistics to release the information to the Cancer Agency comes from the FOIP Act (HIPA does not apply to Vital Statistics):

- *"29(2)(h)(v) of the FOIP Act allows for the disclosure of personal information by a government institution for the purposes of an agreement or arrangement with a local authority. Although there is no formal agreement per se in place with the Cancer Agency, this long standing arrangement between the two bodies for the disclosure of information from Vital Statistics to the CA is clearly an "arrangement", recognized by section 29(2)(h)(v) of the FOIP Act as a proper ground for disclosure without consent.*

. . .

- *Similar to the disclosure from the Person Registry System, the disclosure from Vital Statistics is intended to provide the Agency with information necessary to verify its own registry, in particular to verify whether the patient is alive or has died.*

  Section 16(a)(iii) of the FOIP regulations provides the authority to disclose personal information to verify the accuracy of personal information held by the local authority."[120]

I find that the disclosure of personal health information namely vital statistics information from Saskatchewan Health to the Agency was authorized by section 29(2)(h)(v) of *The Freedom of Information and Protection of Privacy Act.*

G. Disclosure by Saskatoon and Regina Qu'Appelle Health Regions to the Agency

Personal health information of some 300,000 women is disclosed by the two largest health regions in Saskatchewan to the Agency. This includes registration information and the results of Pap test analysis done by the laboratories in those two health region facilities. This is a disclosure from one trustee to another trustee.

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[120] Ibid, pages 5 and 6

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

G. Disclosure by Saskatoon and Regina Qu'Appelle Health Regions to the Agency (cont'd)

As I understand the submissions by the Agency, the disclosure of personal health information of these women by the two large health regions to the Agency is authorized by three different provisions: Section 27(2)(a) and, or Section 27(2)(b) and, or Section 27(4)(j).

It is important to note that under HIPA, if I find that a given disclosure comes within section 27(2) or 27(4)(j), it follows that there is:

- No need for the woman's consent
- No right for the woman to opt-out
- No right to even access information about the disclosure by the trustee, after the fact

The strongest authority for the PPCC would be founded in section 27(4)(j).

1. Applicability of Section 27(4)(j)

This entails 5 discrete elements:

(1) Disclosure must be made for "provision of health or social services to the subject individual".

(2) In the trustee's opinion, disclosure of the personal health information "will clearly benefit the health or well-being of the subject individual".

(3) It is not reasonably practicable to obtain consent.

(4) Recipient (i.e. the Agency) must agree to use the information only for the purpose for which it is being disclosed.

(5) Recipient must agree not to make a further disclosure of the information in the course of carrying out any of the health or social service activities.

I have already discussed the health services provided by the PPCC and find that it satisfies the first element.

I accept that, in the opinion of the two health regions, the disclosure will clearly benefit the health or well-being of the women enrolled in the PPCC.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

G. Disclosure by Saskatoon and Regina Qu'Appelle Health Regions to the Agency (cont'd)

1. Applicability of Section 27(4)(j) (cont'd)

I accept that the 4th and 5th elements can be satisfied by the Agency.

It would not be reasonably practicable for the PPCC to obtain consent. I believe, however, that it is reasonably practicable to obtain consent of Saskatchewan women when those women will have to physically attend at a physician's clinic to provide the Pap test specimen. That point of collection is the foundation for the PPCC. This provides an appropriate time for each woman to be canvassed as to whether they wish to participate in the Program.

2. Applicability of Section 27(2)(a)

The regions collected the laboratory data for the purpose of testing of the Pap specimens and providing a report on the Pap test to a woman's physician. As noted earlier, this would be with the implied consent of the women who presumably agreed to provide the specimen in the first place and would have reasonably anticipated that the specimen would be required to be examined in a proper laboratory.

This would be necessary for the purpose of screening or testing these women for cervical cancer. Given the way that the Agency has been inserted between the regions and the physician for follow-up reporting purposes, this disclosure comes within section 27(2)(a).

I question whether the disclosure by the laboratories to the Agency would have been within the reasonable expectation of the women who provide the specimen in the first place. Nonetheless, I find that this disclosure was for a consistent purpose.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

G. Disclosure by Saskatoon and Regina Qu'Appelle Health Regions to the Agency (cont'd)

3. Applicability of Section 27(2)(b)

I am troubled by the application of section 27(2)(b) to the PPCC. The PPCC is not a service *"requested by the subject individual"*. Is it a service required by Saskatchewan women? One could make a reasonable case that, for the approximate 60% of Saskatchewan women who are appropriately managing their own cervical health with the support of their family physician, the service required by these women does not include the kind of additional work represented by the PPCC. The specimen has already been analyzed by the laboratory in one of the two large health regions. The PPCC will be determining whether the sample was taken appropriately and whether the woman's physician should be doing something different. The quality assurance activities of the PPCC may be seen by some women as important. In the cases of those women we have heard from, this role of the PPCC is not something they requested and what they have learned about the program has not convinced them differently. I have some doubt as to whether PPCC is a service "*required by the subject individual*".

The principal benefits would appear to accrue to those women who were previously not being screened at all or were screened inappropriately. From the material provided by the Agency, this group is significant but is still approximately only 40% of the women in Saskatchewan in the target age group.[121] I recognize the arguments about the statistical importance and population health surveillance value in capturing all women but this appears to move Saskatchewan into new territory. Should all 300,000 Saskatchewan women be treated indiscriminately in terms of a compulsory "enrolment" in a cervical cancer screening program in order to increase participation by the approximate 40% of women who are not being appropriately tested now?

[121] Saskatoon Regional Health Authority has questioned the validity of these statistics but they are the most current statistics we have received from the Agency in this process.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

G. Disclosure by Saskatoon and Regina Qu'Appelle Health Regions to the Agency (cont'd)

3. Applicability of Section 27(2)(b) (cont'd)

This deemed consent provision is clearly inconsistent with the common law principle of patient autonomy. Nonetheless, my role is not to substitute my opinion for the discretionary decision of the medical advisor of the PPCC unless I find that the discretion was exercised improperly. I may be uncomfortable with this exercise of the discretion but I do not find that the discretion was exercised improperly.

Although later in this Report I will consider the legislative history of section 27(2), I have concluded that the Assembly intended to use this provision to facilitate the relatively free flow of personal health information from one trustee to another trustee when both are engaged, to a greater or lesser extent in arranging, assessing the need for, providing, continuing, or supporting the provision of, a service requested or required by the subject individual. I have concluded that the Assembly intended that the elements of section 27(2)(b) should not be given an unduly restrictive or narrow interpretation.

Later in this Report, I will address the question of best practices quite apart from the legislative requirements of HIPA.

I find that the disclosure of personal health information to the Agency from the RQRHA and the SRHA conforms with section 27(2)(a), 27(2)(b) and 27(4)(j) of HIPA.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

H. Is the Agency an Information Management Services Provider?

In addition to citing the three statutory provisions discussed above, the Agency has also asserted that it is contractually bound to collect or disclose the personal health information from the regions for the PPCC. Those agreements have been described earlier in this report.

The Agency asserts that it has a contractual obligation with the SRHA and the RQRHA to maintain without modification or deletion, all cytology and histology records relating to the diagnosis and treatment of cervical cancer. The Agency asserts that the personal identity of women who withdraw from the program could not be removed prior to sending cytology, histology, or colposcopy results to the Agency as they allow the laboratories to cross-reference information over time on their web-based application. Also, to delete a woman's identity from the PPCC also deletes it from the Screening Program for Breast Cancer as it is a common client database.

Data Sharing Schedules #2 and #3 designate the Agency as an "information management service provider". An information management service provider is defined in HIPA as:

> *"A person who or body that processes, stores, archives or destroys records of a trustee containing personal health information or that provides information management or information technology services to a trustee with respect to records of the trustee containing personal health information, and includes a trustee that carries out any of those activities on behalf of another trustee, but does not include a trustee that carries out any of those activities on its own behalf."*[122]

[122] HIPA, supra, note 1, section 2(j)

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

H. Is the Agency an Information Management Services Provider? (cont'd)

The provision for information management service providers is as follows:

> *18(1) A trustee may provide personal health information to an information management service provider:*
>
> *(a) for the purpose of having the information management service provider process, store, archive or destroy the personal health information for the trustee;*
>
> *(b) to enable the information management service provider to provide the trustee with information management or information technology services;*
>
> *(c) for the purpose of having the information management service provider take custody and control of the personal health information pursuant to section 22 when the trustee ceases to be a trustee; or*
>
> *(d) for the purpose of combining records containing personal health information.*
>
> *(2) Not yet proclaimed*
>
> *(3) An information management service provider shall not use, disclose, obtain access to, process, store, archive, modify or destroy personal health information received from a trustee except for the purposes set out in subsection (1).*
>
> *(4) Not yet proclaimed*
>
> *(5) If a trustee is also an information management service provider and has received personal health information from another trustee in accordance with subsection (1), the trustee receiving the information is deemed to be n information management services provider for the purposes of that personal health information and does not have any of the rights and duties of a trustee with respect to that information.*

The Agency has provided detailed analyses of section 18 and how it should be interpreted. The significance of resolving whether the Agency is an information services provider is twofold:

(1) An information management services provider is required to "comply with the terms of the agreement…"

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

H. Is the Agency an Information Management Services Provider? (cont'd)

(2) An information management services provider that is also a trustee that has received personal health information for one of the 4 purposes listed in subsection (1) does not have any of the rights and duties of a trustee.

To qualify as an information management service provider, an assessment must be done, apart from any contractual description or label, to see if the definition or elements of that definition apply.

The question of an information management services provider is important since the scheme of HIPA is to vest in a given trustee clear responsibility for protecting the privacy of a woman and the confidentiality of her personal health information.

It should also be noted that the regions currently disclose to the Agency more personal health information than is required for the operation of the PPCC. The additional data elements are as follows:

- Provider Email address
- Menopausal State
- Hormone Therapy
- Date, LNMP
- Abnormal Bleeding
- Amenorrhea
- Contraception Type
- LNMP Date
- Menopause Date
- IUD
- OCP
- Hormones Type

XVII Relevant Specific Duties of a Trustee (cont'd)

H. Is the Agency an Information Management Services Provider? (cont'd)

These twelve data elements must be treated differently than the data elements essential to the PPCC. These twelve elements remain information controlled by the two major health regions. This data was not provided, nor I find was it intended to be provided to the Agency on a 'trustee-to-trustee' basis. I find that, insofar as the twelve data elements are concerned, the Agency is acting as an "information management services provider" within the meaning of section 2(j) of HIPA.

I find that the Agency is not functioning as an "information management services provider" but as a trustee when it receives women's cervical health information necessary for the operation of the PPCC. The Agency receives this personal health information primarily for purposes of the PPCC and only incidentally to undertake information management services. I interpret section 18(1) to refer to the provision of personal health information primarily for information management services. In the result, section 18(5) is not engaged in respect of this personal health information as the Agency holds the personal health information in question as a trustee.

It would be clearer if HIPA provided for an "affiliate" along the lines of the provisions in HIA[123] in Alberta or an "agent" in PHIPA[124] in Ontario. In those two provinces, an affiliate or agent is someone who acts for, or on behalf of, the custodian (equivalent to a trustee in HIPA) for the purposes of the custodian and not for the agent's or affiliates or agent's own purposes. [125]

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[123] HIA, note 101, section 1(1)(a) and section 62

[124] The *Personal Health Information Protection Act, 2004*, S.O. 2004, c. 3, Sched. A, section 2

[125] HIPA does provide for an affiliate but that is defined as an affiliate under *The Regional Health Services Act*. The latter statute defines "affiliate" as a person who immediately before the coming into force of this section, is the operator of a hospital approved pursuant to *The Hospital Standards Act* or a not-for-profit special-care home licensed pursuant to *The Housing and Special – care Homes Act*, and includes any successor to that operator but does not include a regional health authority or a prescribed person.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

H. Is the Agency an Information Management Services Provider? (cont'd)

After considering these materials, I take the intention of the Saskatchewan Legislative Assembly to be that the conveyance of personal health information to an information management services provider would be a 'use' and not a 'disclosure' for purposes of HIPA.

1. What is the significance of the contracts between the Agency and the Two Health Regions?

The Agency asserts that its 'hands are tied' by reason of the agreements made with the two health regions that do not accommodate an opt-out. I have two observations to make about this assertion:

(1) The agreements have all been entered into within the last 3 years at the same time the final adjustments were being made to HIPA to pave the way for proclamation. I expect that all 3 trustees must be taken to have recognized that any agreements entered into would have to be subject to HIPA and might require modification to conform to HIPA as it is interpreted by our office and the Courts.

(2) In Saskatchewan there is a remarkable degree of collaboration between the Agency and the two large health regions. Since all three bodies are trustees and therefore subject to the same HIPA constraints and since all three bodies will share an interest in promoting patient confidence in all of their activities, I encourage them to review their contractual arrangements to determine how this might be revised.

I recommend that the Agency and the two health regions review their contractual arrangements to determine what changes would be required to accommodate a meaningful opt-out procedure. This could be done in a way that allows the regions and a woman's physician access to data necessary to manage her health but to deny access to that data by the PPCC in the event of an opt-out.

Any adjustments, to the extent they are required, should be to the Agency's arrangements with the two health regions rather than to the privacy rights of Saskatchewan women.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

I. Disclosure by the Agency to Regional Health Authorities

The Agency discloses personal health information back to the health authorities pursuant to section 27(2) and clause 14 of the Data Services Appendix A to the Master Data Sharing agreement.

This disclosure would be subject to the following provision in the System Access Privacy Pledge that would have been signed by an employee in either of the health regions:

> *"I will only access and use the system(s) as necessary for the purposes of viewing and accessing the System with a view to determining whether any changes or modifications may be required to made to the System to meet the Region's needs. This means, for greater certainty, that I will only access personal health information available on the System for which I have a strict need to know in connection with the above purpose. I will not access any personal health information for which I do not have such a need to know.*
>
> *I will safeguard and will not disclose or share my passwords, User ID's, clearance badges, access cards, keys or other codes or devices assigned to me (or created by me) that allow me to access to the System. I accept responsibility for all activities undertaken using such codes and devices.*
>
> *I understand that the obligations contained in this pledge are intended to be complimentary to any similar obligations I may have agree to in other SCA/Region policies or as may be imposed by law or applicable professional ethical obligations or standards. To the extent of any inconsistency between such obligations, the obligations imposing the highest confidentiality standard shall govern.*

In addition, the Data Sharing Schedules between the two health regions require that *"Any data extraction by* [health region] *will not be done without first discussing with SCF on appropriate times, tolls, security and methods."*

I find that the two health regions have established policies and procedures as required by section 27(3)(a).

I find that the disclosure of personal health information related to the PPCC by the Agency to regional health authorities conforms with section 27(2) of HIPA.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

J. Disclosure by the Agency to Family Physicians

The Agency has urged us to consider the following factors in analyzing this transaction:

(1) The PPCC supports care providers in providing quality care. This PPCC fields telephone calls on what the physicians should be doing; provides new point of accessing information and can point them in the right direction; provide education/support for women; and pre/post communication is guaranteed. Also, it was suggested to us that some physicians will only "let you know if there is a problem". It was also suggested that patients will also not always call to check in if they have not heard anything. Thus, getting a letter may be reassuring.

(2) By including all test results, the adequacy/timeliness of follow-up can be determined. This information is then used to develop communications/education materials and strategies directed at the medical community.

(3) Medical clinics do not have the supportive infrastructure to allow recruitment and recall of patients and/or ensuring follow-up occurs. The PPCC system was established to provide a systemic ability for ensuring women receive required care. Doctors do not have time before every test to explain everything.

Physicians now may ask the Agency to track down a patient and ensure that follow-up has occurred. Before, there was no record of follow-up, so patients may not receive appropriate treatment. We were advised that communications between patients and doctors are not always good.

The Agency discloses to family physicians when it follows up on abnormal results from Pap tests. The underlying purpose is to help facilitate the timely assessment of whether a woman requires further health services i.e. where screening uncovers an abnormality.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

J. Disclosure by the Agency to Family Physicians (cont'd)

There is authority for this disclosure under section 27(2)(a). The purpose of the collection by the physician initially was to allow the Pap specimen to be tested to enable the physician to provide the patient with his or her diagnosis, and treatment where appropriate. In other words, this disclosure is for the purpose for which the information was collected.

This disclosure is also authorized under section 27(2)(b) since the disclosure is for the purpose of arranging, assessing the need for, providing, continuing, or supporting the provision of, as service requested or required by the woman.

As with other transactions relying on section 27(2), the trustee must first meet the requirements of section 27(3).

The Agency provides notification to Saskatchewan women of their Pap test results. I have been advised that the program is organized so that notice is first sent by the regions to the physicians. The Agency then sends notice to the woman 14 days after notice to the physician. Nonetheless, I have heard from a number of women who received a letter from the Agency notifying them of an "abnormal" test result before they heard from their physician. That was their first and only notice of an abnormal test result. They were then in some understandable distress until they could speak with their physician.

I am in no position to determine whether this experience reflects a failure of the Agency to follow its sequence of correspondence or inefficiency in the physicians' offices and tardiness in following up with their female patients. Either way, this appears to be a singularly unsatisfactory situation.

XVII RELEVANT SPECIFIC DUTIES OF A TRUSTEE (CONT'D)

J. Disclosure by the Agency to Family Physicians (cont'd)

There is obviously a need for further dialogue between the College of Physicians and Surgeons, the Saskatchewan Medical Association and the Agency to ensure more satisfactory communication with these women.

K. Access

Subject to Section 38, and payment of a reasonable fee, on making a written request for access, an individual has the right to obtain access to personal health information about him or herself that is contained in a record in the custody or control of a trustee.

Although we have heard from many women with different concerns about the PPCC, I believe we have heard of only one woman who wanted to exercise her right to access what personal health information the Agency had about her. We were advised by this woman that she attended at the Agency's offices and obtained the information that she sought.

I make no recommendations with respect to the access rights of Saskatchewan women in connection with the Program apart from addressing confusion in forms for access and forms for disclosure.

In keeping with our other recommendations to increase transparency in the PPCC the Agency should make the access process much more transparent to Saskatchewan women.

XVIII A DISCUSSION OF CONSENT IN HIPA

The key transaction in terms of the PPCC is the disclosure of the personal health information by the two health regions to the Saskatchewan Cancer Agency. As noted earlier, this is not mandated by *The Cancer Foundation Act*.

To the extent this is authorized, the authority must be found in either the deemed consent in section 27(2) or in one of the specified exceptions to the consent requirement in section 27(4).

Given the importance of consent, it is relevant to understand the history that led to the current section 27(2) of HIPA.

A. Legislative History of Section 27(2) of HIPA

I have carefully reviewed the Hansard record of the legislative debates with respect to Bill 29 that eventually became HIPA. I have attempted to determine whether there was any specific consideration of section 27(2) and its impact on the right of privacy guaranteed by the Charter. I was also interested in whether there had been explicit debate over the application of HIPA to province-wide surveillance activities.

This review included a search for any reference to HIPA in Question Period debate.

Bill 29 was introduced at First Reading by Minister J. Junor on April 26, 1999. She stated, in part, as follows:

> *"Mr. Speaker, I'm pleased to rise today to move second reading of The Health Information Protection Act. Mr. Speaker, the protection of personal health information is important to every citizen in this province. Personal privacy is something we all expect from the health system. Historically people gave private information to health providers because they trusted those providers to keep the information private and to use it only when appropriate to provide care.*
>
> *The people of Saskatchewan trust their health professional to protect their personal health information. They trust their doctors and nurses to use the information wisely. They trust hospital staff to use only...to only use personal information for reasonable purposes associated with care. They trust laboratory technicians to keep the results of lab tests private. They trust dentists and pharmacists, health records technicians, and all in the health system to protect the records of their personal health.*

XVIII A Discussion of Consent in HIPA (cont'd)

A. Legislative History of Section 27(2) of HIPA (cont'd)

In short, Mr. Speaker, the people of Saskatchewan trust their health professionals to handle their personal health information with respect for their right to personal privacy. The people of Saskatchewan deserve no less.

However, Mr. Speaker, the demand for information needed to provide health services is growing. As the volume of information about us grows, as we ask for more tests and additional treatments, as the demands on the health system continue to increase, so too does the demand for information exchange. With increased demands for information comes an increased risk to the privacy of the individual. And, Mr. Speaker, the people of Saskatchewan demand that their personal health information continue to receive the protection they expect.

That is why, Mr. Speaker, The Health Information Protection Act is so important. It ensure that even in the fast moving health system of today the tradition of respecting individual privacy will continue into the future. In fact, Mr. Speaker, we believe that this new important legislation adds significantly to the protection we have all come to expect from the health system.

Mr. Speaker, The Health Information Protection Act is about the rights of individuals to protect their personal health information. The Act enshrines in legislation certain rights that every person in this province has in regard to their personal health information.

The Act then sets out the duties and responsibilities of government and the health system to ensure that those rights are respected. Mr. Speaker, The Health Information Protection Act will ensure that people's privacy rights are protected.

. . .

Since 1995, the Department of Health has worked to develop a comprehensive framework of health information management principles and broad policies within the public sector. These principles, Mr. Speaker, are consistent with the best national and international information management principles in the world today.

These principles include: accountability to the individual; collection, use, and disclosure of personal health information only for legitimate health purposes; the right of individuals to access their own information; and that health professionals hold personal health information in trust for individuals, and manage it accordingly.

. . .

XVIII A Discussion of Consent in HIPA (cont'd)

A. Legislative History of Section 27(2) of HIPA (cont'd)

Mr. Speaker, this legislation ensures that even on a computerized network such as SHIN (Saskatchewan Health Information Network), it is the individual and their health provider who controls what happens to the record. The people of Saskatchewan have told us that they are concerned about unauthorized access to personal information if their complete health record is on a computer network.

Mr. Speaker, this legislation clearly states that access can only be given to those who need to know the information to provide a service. Even then, Mr. Speaker, there must be consent from the individual in most circumstances before access can be given. Mr. Speaker, there will be surfing of records on SHIN [126]

Saskatchewan people told us that health information must be secure. It must be protected from unwanted access and it must be accurate and available when it is needed.[127]"

The original section 27 of Bill 29 provided, in part, as follows:

27(1) A trustee may disclose personal health information to any person for any purpose with the express consent of the subject individual.

(2) Subject to subsection (4) and sections 28 and 29, a trustee shall not disclose personal health information in the custody or control of the trustee except with the consent of the subject individual.

(3) Consent to the disclosure of personal health information must be express consent, except where it is reasonable for the trustee to infer that the subject individual would consent to the disclosure and where the disclosure is being made:

(a) for the same purpose as the purpose for which the information was collected by the trustee or for a purpose that is consistent with that purpose;

(b) where the subject individual is a patient of the trustee or a patient or resident in a health care facility, to a member of the subject individual's immediate family or to anyone else with whom the subject individual has a close personal relationship, if the disclosure:

(c) to the extent that is necessary to obtain payment for health services provided to the subject individual; or

(d) in any cases prescribed in the regulations …

[emphasis added]

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[126] Saskatchewan Health advises that the line should read "there will be no surfing of records on SHIN". That is the line contained in the prepared speaking notes and was either inadvertently dropped by the Minister or missed in the recording of *Hansard*. According to the Department, the Minister and the Department have always been clear that it will not be possible to "surf" records on SHIN. Records on SHIN will only be available on a need-to-know basis within the health sector to support the delivery of health services.

[127] Saskatchewan *Hansard*, April 26, 1999, pages 761-762

XVIII A DISCUSSION OF CONSENT IN HIPA (CONT'D)

A. Legislative History of Section 27(2) of HIPA (cont'd)

At deliberation by the Committee of the Whole, Minister Junor stated, in part, as follows:

> *"The Bill allows people to withdraw their consent for having their information stored anywhere. How it is applied when it is up and running as a system, whatever system we do see it running as, that is an implementation issue for how it will be applied rather than how the Act pertains to it, that you can or cannot what you do consent to, implied, express, or without consent.*[128]"

Also, in Committee, the following exchange took place between Minister Junor and Mr. D'Autremont (Member for Cannington):

> Mr. D'Autremont: - *"Would it be possible for an individual to give consent for hospitals and doctors to have access to that information but that nursing homes and home care and mental health don't have access to that information?"*
>
> Hon. Ms. Junor: - *"Technically you could do that. How feasible it would be for an information manager to do it, would be what we would see with whoever picks it up as an information manager, how their systems would allow that to happen; but technically the Act does allow that to happen."*[129]

A further exchange between those same two members is illuminating:

> *Hon Ms. Junor: - "First of all, any person has the right to...not to have...to say they do not want their information stored on any information system. Secondly, they can withdraw that consent at any time."*[130]

Also in Committee, the following exchange occurred between the Minister and Mr. Harvey McLane (Member for Arm River):

> *Mr. McLane: - "Will consent then be a bit like negative billing-negative consent? If you don't expressly say no, I don't want my information used, then it may be misconstrued that that's fine, go ahead and use it by the trustee."*

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[128] Saskatchewan *Hansard*, April 28, 1999, page 873
[129] Ibid
[130] Ibid, page 875

XVIII A Discussion of Consent in HIPA (cont'd)

A. Legislative History of Section 27(2) of HIPA (cont'd)

> *Hon. Ms. Junor: -- "That's exactly the opposite. I mean the express consent is in writing but there's also an onus on providers in the Act that there is some way to educate the public that this is what they're expressing their consent for.*
>
> *I mean right now we look at consent forms for surgeries, for admissions to hospitals. You have informed consent, and that's what we …this Bill will also deal with informed consent. So we expect people to be informed about what they're consenting to, or actually asking to have their information not put on the system; that they will be informed."*[131]

The Assembly dealt further with *The Health Information Protection Act* in the spring of 2003. Bill 28, *The Health Information Protection Amendment Act, 2003* was introduced, debated and passed by the Assembly.

In fact, what the 2003 amendment package did was to eliminate the inferred or implied consent and substitute deemed consent i.e. no consent for the collection, use and disclosure of personal health information by trustees for most health related purposes.

In introducing Second Reading of Bill 28, Minister Nilson explained the purpose of the bill as follows:

> *"Thank you Mr. Speaker. Mr. Speaker, I'm pleased to rise today to move second reading of The Health Information Protection Amendment Act. Mr. Speaker, the protection of personal health information is important to every citizen in this province. Personal privacy is something we all expect from the health care system.*
>
> *However, Mr. Speaker, Saskatchewan people also want their health care providers to have all of the information they need to make the best possible decisions with respect to patient care. Mr. Speaker, people give their personal health information to health care providers because they trust those providers to keep that information private and to use it only when appropriate.*
>
> *Mr. Speaker, there's a growing need for more and more personal health information in the health care system today. The volume of individual's health information increases as we have access to more tests and treatments, and so does the demand on the health care system continue to more effectively exchange information.*

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[131] Ibid, page 876

XVIII A Discussion of Consent in HIPA (cont'd)

A. Legislative History of Section 27(2) of HIPA (cont'd)

Improved communication between health care providers allows for faster diagnosis and more effective treatment. As technology improves, our ability to share health information increases. Therefore it is all the more important that we must ensure that individual patient privacy is protected.

That is why, Mr. Speaker, we introduced The Health Information Protection Act in 1999. This Act sets the ground rules for protecting personal health information. It is designed to safeguard the privacy of people's health information while ensuring that health care providers are able to share information as needed in order to give the highest quality health care.

Since the introduction of The Health Information Protection Act in 1999, we have worked closely with our partners in the health care system in extensive consultations on the Act. Our gaol has been to achieve the right balance between the need for personal privacy and the need for timely, accessible health information to be used by our health care professionals.

During the extensive consultations since 1999, our health care partners identified certain issues. They felt that health care professionals might not be able to easily access, use, and share important information during the treatment of their patients.

Last winter, the winter of 2001-2002, a formal consultation document on the amendments was distributed to the Saskatchewan Health Information Network, the Saskatchewan Medical Association, the regional health authorities' chief executive officers and the Chairs of their boards, the health professional regulatory bodies, the Saskatchewan Association of Health Organizations and its affiliates, deputy ministers of government departments, other government institutions, unions, as well as other stakeholders and people across the province.

We heard and acknowledged their comments, Mr. Speaker, and decided that the best course of action was to amend The Health Information Protection Act. The result is the Bill before you today.

We resolved the issues that would clarify and strengthen the Act while being true to its original intent. Mr. Speaker, we will now have a strong piece of legislation to effectively support the delivery of quality health care services for people across Saskatchewan while maintaining the right to privacy and the protection of personal health information. We are adding protection for personal health information and we are ensuring that strong, consistent rules are in place throughout the health care system for that information.

XVIII A Discussion of Consent in HIPA (cont'd)

A. Legislative History of Section 27(2) of HIPA (cont'd)

With these amendments, The Health Information Protection Act will require health care providers and others entrusted with personal health information to collect, use, and disclose personal health information to collect, use and disclose personal health information only as necessary and in accordance with strict policy and procedures consistent with the Act to protect the integrity and accuracy and confidentiality of personal health information, and to provide security for personal health information, and to have policies and procedures in place about retention and destruction of personal health information.

And, Mr. Speaker, in the event that a comprehensive electronic health record is created, The Health Information Protection Amendment Act ensures that patients will have the power to block access to their health information once that system is in place.

Organizations that contract with others for information management services for personal health information must enter into binding legal agreements to ensure that health information is kept secure and private. Current levels of information protection are being maintained or strengthened. Health care professionals will have access to the information they need to provide the best possible services.

Failure to live up to the Act's requirements could result in stiff penalties, including imprisonment and fines up to $50,000 for an individual or $500,000 for a corporation.

Patients will be better informed about the use of their personal health information and will have more confidence in the integrity of the system. They can bring their concerns regarding personal health information to the attention of the Information and Privacy Commissioner.

This amended Act, Mr. Speaker, provides Saskatchewan with an excellent privacy framework which will enhance and improve the confidentiality surrounding personal health information in Saskatchewan.

With that, Mr. Speaker, I'm pleased to move second reading of The Health Information Protection Amendment Act."[132]

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[132] Saskatchewan *Hansard*, May 14, 2003, pages 1086-1087

XVIII A Discussion of Consent in HIPA (cont'd)

A. Legislative History of Section 27(2) of HIPA (cont'd)

There is a particularly instructive exchange in the Assembly between the Minister and Ms. Atkinson (Member for Saskatoon Nutana) on June 4, 2003[133]:

> *Ms. Atkinson: - Thank you very much. Mr. Speaker, in my remarks regarding this Bill I indicated to the minister I wanted him to consider the notion of certain medical procedures not forming part of the person's comprehensive health record, and in fact, an individual would have the right to indicate that certain medical procedures not form part of that electronic record. And I'm wondering whether the minister has considered that, and if he has, what amendment does he propose to this legislation, for instance to allow women to keep from the electronic record, as an example, a therapeutic abortion?*
>
> *Hon. Mr. Nilson: - The member has asked that I consider a House amendment to this particular piece of legislation, and I would say that I have considered very carefully, a House amendment that would try to deal with some of the issues that the member has raised. But at this stage I am going to stay with the legislation as it is and I will explain why.*
>
> *At this point in the stage of technology the best way for providing the kind of protection for the individuals is to allow the data to be collected and then put a limit on the ability to access it. So basically what we're saying is that we will provide the ability to put the restriction on the disclosure of the information, not on the collection of the information.*
>
> *Now, why do we take that position, or why do I take that position after listening to advice from many people throughout the health system? I take that position because at this stage the ability to set up electronic methods of cutting off the entry of information into the system is not technologically possible to do it. Now that's not to say that three years or five years or ten years from now there may be some ways of doing that, but at this stage it's not possible.*
>
> *And it's this particular point that has been the challenge for our whole health system-the regional health authorities, the medical profession, others-who have said that to try to implement a system that allows for the non-collection of information of a particular patient as it relates to only specific parts of the information about that particular patient is unduly or almost impossible to do; whereas a rule that protects absolutely the disclosure of that total record of that patient is something that would work.*
>
> *And so we are sticking with this particular amendment as it is now. We will continue to examine this issue because we know that it's an issue that is raised in the community. But after consultation throughout the health system in Saskatchewan with the health professions and with the people who are trying to manage this system, the proposal as we have it is the one that we intend to go with."*

[133] Saskatchewan *Hansard*, June 4, 2003; page 1441

XVIII A Discussion of Consent in HIPA (cont'd)

A. Legislative History of Section 27(2) of HIPA (cont'd)

I note a similar discussion in the Assembly on May 29, 2003.[134] Even though the reference is specifically to the statutory creature known as "the comprehensive health record" in section 18.1 of HIPA, I find the same comments are relevant to this review of the PPCC. In fact there is some additional privacy protection in that a woman can demand that her comprehensive health record not be included in Saskatchewan's SHIN program although this is an all or nothing proposition. If a woman wishes that only certain information be excluded from her comprehensive health record then she would be in the same position as any Saskatchewan woman who does not wish her personal health information collected, used or disclosed by the PPCC.

The 2003 amendments to HIPA also aligned Saskatchewan more closely with the health information laws in Alberta and Manitoba and the way those laws permitted much collection, use and disclosure of personal health information without consent.

Leaving aside for the moment the question of the general statutory duties of a trustee, it is apparent to me from *Hansard* that the government of Saskatchewan intended that the deemed consent, or no consent provision in section 27(2) of HIPA, would eliminate any need to obtain a woman's consent in those circumstances. The Legislative Assembly, by passing Bill 28 in the spring of 2003, must be taken to have similarly intended to dispense with any requirement for a woman's consent in the very wide circumstances of section 27(2).

I find that, by reason of section 27(2) of HIPA, a trustee that has otherwise complied with all of the general duties of a trustee enumerated in sections 9, 16, 19 and 23 is not required to obtain consent of the woman to collect, use or disclose information related to the Pap test for purposes of the PPCC.

[134] Saskatchewan *Hansard*, May 29, 2003; page 1322

XVIII A DISCUSSION OF CONSENT IN HIPA (CONT'D)

A. Legislative History of Section 27(2) of HIPA (cont'd)

Having determined that section 27(2) of HIPA was intended to avoid any consent requirement, does that end this line of inquiry?

I have determined that it does not for three reasons:

(1) In the view of this office, HIPA creates a floor and not a ceiling. There is no statutory prohibition against a trustee employing either express consent or implied consent wherever the trustee determines that it is appropriate in the interests of promoting greater patient confidence in its work. This would be analogous to the approach taken by the Saskatchewan government to its *Overarching Personal Information Privacy Framework for Executive Government.*[135] That initiative recognizes existing statutory requirements for collection, use and disclosure of personal information but intends to "*raise, for individual citizens, the level of protection of their personal information*". Given the particular sensitivity of personal health information, I expect that the Assembly would be open to considering how to strengthen its legislation.

(2) I also view the mandate of this office as one of offering advice and commentary on privacy 'best practices' above and beyond a literal interpretation of the relevant statute(s). This would be consistent with the role played by the Privacy Commissioner of Canada and Information and Privacy Commissioners in other Canadian jurisdictions. The Minister of Health has indicated in the Assembly that notwithstanding the passage of Bill 28 his Department would continue to examine the issue of opt-out "*because we know that it's an issue that is raised in the community.*"

[135] Overarching, supra, note 88, page 3

XVIII A DISCUSSION OF CONSENT IN HIPA (CONT'D)

A. Legislative History of Section 27(2) of HIPA (cont'd)

(3) As an officer of the Legislative Assembly, I am required to offer my advice to the Assembly if I believe that there is a significant risk that the courts may find that HIPA violates the *Charter of Rights and Freedoms*. If that were to occur, the options available to the courts are quite limited. A court in that situation would not be able to precisely redesign the consent mechanisms in HIPA and would be most likely to either strike down the offending portion or suspend its operation. If the Assembly shares my concern with section 27(2), I expect that it would prefer to consider a more nuanced solution authored by the Assembly than would result from any court decision.

When Bill 28 was being debated in the Assembly in 2003, I cannot find any mention in *Hansard* of the *Canadian Charter of Rights and Freedoms* and its impact on the deemed consent provision that was a key element of the amending bill. It is clear that Saskatchewan Health was responding to concerns from the health sector and health care providers. It is not clear that there was public consultation on the move from implied consent to deemed consent. At the end of the day, privacy, as protected by the Charter, is a right of individuals in this province and not something that can satisfactorily be resolved without engaging citizens in that discussion.

B. What would be appropriate as a Best Practice?

From a 'best practices' standpoint, the 'gold standard' in terms of consent would be express, informed, voluntary consent sought and provided prior to the collection, use and disclosure of personal health information. Apart from what HIPA requires, I am persuaded by the Agency that express consent as contemplated by section 6 of HIPA is neither reasonable nor workable.

XVIII A Discussion of Consent in HIPA (cont'd)

B. What would be appropriate as a Best Practice? (cont'd)

On the one hand, one might argue that cancer registries in the Canadian experience routinely require mandatory reporting of a cancer diagnosis to the registry. There is no consent requirement and no provision to opt-out. That is certainly the case with the Saskatchewan cancer registry maintained by the Agency under the provisions of *The Cancer Control Act*.

To use the model of the cancer registry, however, would not reflect the qualitative difference between a registry of those Saskatchewan residents already diagnosed with cancer and the 300,000 Saskatchewan women who are on the list solely by reason of their gender and age. Thankfully, the vast majority of these 300,000 women do not have, and will not in the future, have cervical cancer.

I am impressed with the New Zealand experience and health research experience that suggests that to require explicit consent would effectively compromise a valuable cancer prevention tool. I therefore believe it would be a mistake to view express consent for participation in the PPCC Program as a best practice.

C. Opt-out Consent

On the other hand, there must be some way of accommodating the right of a woman to exercise a measure of control over this sensitive personal health information. One way of doing that would be through a form of opt-out consent. This is usually in the context of an implied consent model whereby the trustee is entitled to assume that it has consent to collect, use and disclose personal health information unless and until the individual registers objection. By "opt-out" I mean giving a woman information as to how her personal health information will be collected, used and disclosed for purposes of the PPCC and giving her a clear and simple means of opting out of the PPCC. This very kind of opt-out appeared to be appropriate to the Saskatchewan Task Force for Cervical Cancer Screening when it produced its 1999 report.

XVIII A DISCUSSION OF CONSENT IN HIPA (CONT'D)

C. Opt-out Consent (cont'd)

I have determined that an implied consent model would satisfactorily respect the privacy rights of Saskatchewan women without substantially impairing the PPCC. This would also serve to align our Saskatchewan practice with PIPEDA and the Pan-Canadian Framework, discussed later in this Report.

The *Canadian Medical Association Health Information Privacy Code* is very clear on the question of implied consent:

> *"5.7 Consent can only be inferred in the case of primary purposes, and for primary purposes alone; collection, use, disclosure or access thus authorized must be limited either to the known expectations of a particular patient or to what the reasonable person in similar circumstances would likely believe necessary to receive health care.*
>
> *5.8 Implied consent does not deprive the patient of the right to refuse consent or the right to challenge the provider's finding of implied consent."*[136]

I find that the following positions attributed to the United Kingdom Information Commissioner make good sense:

> "Implied consent: -- *"In most cases where consent is required in order to satisfy the common law duty of confidence, the Commissioner accepts that implied consent is valid. She does not accept that implied consent is a lesser form of consent. Provided that...fair collection information...has been provided at an appropriate time, including information as to whether data must be supplied or whether it is optional to do so, and the data subject accepts treatment and does not object to any uses or disclosures of data, then the Commissioner will consider that valid consent has been given."*
>
> Option to opt-out: -- *"An opt-out should be provided wherever patients have a real choice as to how their data are to be processed or wherever this is an appropriate means of gaining consent. In addition, data subjects also have rights to object to the processing of their data whether or not they have been given an opt-out"*
>
> *The UK Act and the Commissioner's interpretation are in line with the international drift of these issues and indeed in many respects are leading it."*[137]

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[136] Canadian Medical Association. *CMA Health Information Privacy Code*, October 20, 1998, page 11 (available on-line: www.cma.ca/index.cfm/ci_id/3216/la_id/1.htm) (hereinafter "CMA Code")

[137] "*Learning from Experience*", supra, note 55, page 16

XVIII A DISCUSSION OF CONSENT IN HIPA (CONT'D)

C. Opt-out Consent (cont'd)

Of course we are not dealing with a common law situation in Saskatchewan since HIPA obviously displaces the pre-existing common law. In terms of best practices however I find this approach attractive.

I have also found useful a further document, *The Canadian Strategy for Cancer Control: Screening Working Group Final Report* of January, 2002. The authors of that document state, in part, as follows:

> *"Participation in a screening program should be on the basis of a realistic understanding of the harms and benefits of screening and the manner in which health information will be managed. Participation should be voluntary with the ability to opt-out at any time."* [emphasis added] (page 10)

I also refer to the document, *Building for Success: A Pan-Canadian Forum on Cervical Screening*, Ottawa, Nov. 21-22, 2004 on page 86 the following appears:

> *"There has been recent interest in the issue of informed choice about screening. The National Screening Committee on colorectal Screening recommended that informed consent be obtained for screening, with information provided on the risks and benefits of the entire screening cascade (not just the initial test),* in order to protect the rights of Canadians and to maximize the benefits of screening. *Ultimately, such approaches for cervical screening must be confidence-building for the client while being practical for the health services provider to deliver."* [emphasis added]

The *Canadian Medical Association Health Information Privacy Code* includes a statement that ought to assist in considering what would be a best practice:

> *"5.12 Although all health information is sensitive and should be treated as such, the more sensitive the health information is likely to be, given what is known about the circumstances or preferences of the patient, the more important it is to ensure that consent is voluntary and informed."*[138]

[138] CMA Code, supra, note 136, page 11

XVIII A Discussion of Consent in HIPA (cont'd)

C. Opt-out Consent (cont'd)

I note also the following statements that appear in the Principle 5 -- Consent in the Canadian Medical Association Health Information Privacy Code:

> *"The patient's ability to decide with whom he or she will share information is crucial for the protection of the right of privacy and for the preservation of trust in the therapeutic context. Only the patient's consent to health information collection, use, disclosure and access for the primary therapeutic purpose can be inferred. Except for the very limited non-consensual purposes addressed in this Code, any other collection, use, disclosure or access requires express consent. Nonconsensual collection, use, disclosure or access infringes the right of privacy and compromises the trust of the fiduciary relationship. To satisfy the requirement that consent be informed, the patient must have, or by reasonable means be provided with, knowledge about the potential for subsequent nonconsensual collection, use, disclosure or access before he or she confides any information."*[139]

I have found that there is some helpful guidance provided by work that has been done in the health research community and also the experience with cervical cancer screening in New Zealand.

D. The New Zealand Experience

I have found the experience in New Zealand to be helpful for several reasons. One is that the experience is particularly rich since they have been in the business of considering, implementing and amending cervical cancer screening programs since the early 1990's. In addition, New Zealand has recently completed a thorough Cervical Cancer Audit that rigorously evaluates the approach taken in that nation to consent.

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[139] Ibid

XVIII A Discussion of Consent in HIPA (cont'd)

D. The New Zealand Experience (cont'd)

New Zealand started off with the requirement for explicit consent from women before they were registered in the cervical cancer screening program. The result was a low level of participation that undermined the utility of the entire program. In 1993 it was changed to an opt-off system that meant that women were automatically enrolled in the program but were permitted to choose to remove particular Pap test results from the register. Two years ago, that program was further amended to substitute a much wider kind of opt-out so that women can opt-off the entire program rather than removing individual results only. When the New Zealand government contemplated eliminating the explicit consent or opt-in requirement, the Privacy Commissioner observed that:

> *"Any such change should include the ability of an individual affected to "opt out" of the group whose information will be so used or disclosed, and this option should be exercisable easily and at any time".*[140]

Those latest amendments permit a woman, at any time, to opt-off the National Cervical Screening Program by notifying the National Cervical Screening Program manager. The manager has a duty to send a notice to the woman confirming her cancellation. Any information relating to the woman's screening history must be deleted from the National Cervical Screening Program register and any information held by the program in hard copy must be either returned to the woman or destroyed.

In New Zealand, each time a woman provides a Pap specimen, the physician must tell her that copy of the Pap test result will be sent by the laboratory to the Register unless she chooses not to have it recorded there. Similarly, any biopsy result will be sent to the Register unless the woman objects. If a woman exercises her right of "opt-off", the physician must give her a written notice confirming her choice.

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[140] *Improving the National Cervical Screening Programme*, 23 July 2001, page 4 (available online at http://www.privacy.org.nz)

XVIII A Discussion of Consent in HIPA (cont'd)

D. The New Zealand Experience (cont'd)

The physician would then send a written notice, (usually a sticker) to the laboratory with the Pap specimen and make a record in his or her medical notes. Subsequently, enrolments in New Zealand went from 20-40% to 80-99%. This exceeded the projected targets set in the 1996 policy and compares well with cervical screening programmes internationally.

I should note that New Zealand also has a Cancer Registry and there is no provision for a cancer patient opting out of that Registry.

E. Manitoba

In Manitoba, I understand that there is an opt-out feature for women. The brochure published by the Manitoba Cervical Cancer Screening Program includes the following:

> *" Can I opt out of the Registry?*
>
> *Yes, You may decide that you do not want to participate in the Manitoba Cervical Cancer Screening Registry.*
>
> *To have your name taken off the Registry, you should complete and sign the form found in this pamphlet and mail or fax it to the Manitoba Cervical Cancer Screening Program.*
>
> *Remember, if you decide to opt out, you will not receive the benefits that being included in the Registry will provide.*
>
> *Can I opt back into the Register?*
>
> *Yes. To have your name added into the Registry once you have opted out, please telephone our office for more information on how to register.*
>
> *Please note that Pap smear results and follow-up tests will only be available to the Registry from the date that you re-enter the program"*

Cancer Care Manitoba has produced a brochure, Manitoba Cervical Cancer Screening Program Registry-Facts & Information. This brochure includes a simple opt-out Form that can be cut out and mailed or faxed to the agency.

XX A DISCUSSION OF CONSENT IN HIPA (CONT'D)

F. Alberta

The Alberta Cancer Board operates a cervical cancer screening program similar to the Saskatchewan model in that there is no genuine opt-out provision. I am advised that the office of the Alberta Information and Privacy Commissioner is currently investigating a breach of privacy complaint concerning the Alberta cervical cancer screening program although no report has yet been issued.

G. Position of the Agency on Possibility of Opt-out

During our meeting with the Agency and its legal advisors on October 19, 2004 we canvassed the specific consequences that, in the Agency's view, would flow if the PPCC provided for a full opt-out at the election of any individual woman. The focus was on the likely consequences in the event that a woman's personal health information was purged from the PPCC database. The points raised by the Agency are bolded and italicized.

> ***Those women would not be recalled for regular Pap testing and would not be advised by the Agency of the results of their Pap tests.***
>
> As noted earlier in this Report, the Agency's materials indicate approximately 60% of Saskatchewan women were tested appropriately before the implementation of the PPCC. If the PPCC hadn't undertaken the responsibility of notifying women of their Pap test results, we expect they would be getting notification from their physician. I am of the view that a woman should always have the option to decide for herself whether she wishes to manage her own health in conjunction with her family physician.

XVIII A DISCUSSION OF CONSENT IN HIPA (CONT'D)

G. Position of the Agency on Possibility of Opt-out (cont'd)

There would be no tracking overdue follow-up of non-normal Pap test results, initially with the health care provider and subsequently with women. Protocols for following non-normal results should be in accordance with the Programmatic Guidelines for Screening for Cancer of the Cervix.

The primary responsibility for follow-up of non-normal test results continues to be physicians as it was before the PPCC. Any family physician who believes that he or she is not able to provide the appropriate follow-up would presumably encourage the female patient to not withdraw from the PPCC. It may provide a good reason to have this conversation with the patient at the time of the initial Pap test and would not need to be repeated normally. If it can be established that certain physicians are not following the appropriate protocols this ought to be a matter for the College of Physicians and Surgeons to address.

There would be an incomplete database consisting of cytology, histology and colposcopy information on women who have Pap tests and follow-up in Saskatchewan.

An opt-out would not prevent the two health regions from establishing a database under their control to ensure physicians had access to complete information about their patients and that may involve an information management services provider under their control. The key is that this would be a "use" and not a "disclosure" under HIPA.

I understand that the two health region laboratories will continue to have the relevant personal health information including histology and cytology data they have also sent to the Agency. This will be in an archived format which makes it difficult but not impossible to retrieve. It is there for disaster recovery. It is currently not possible without a great deal of difficulty for the regions to furnish a physician with all of the relevant historical data for a particular woman prior to June, 2004. The assertion of the Agency assumes that the regions and the Agency cannot, or will not, modify their agreements to accommodate a full opt-out feature.

XVIII A Discussion of Consent in HIPA (cont'd)

G. Position of the Agency on Possibility of Opt-out (cont'd)

There would be a constraint on quality assurance processes and the provision of quality assurance reports and audits with respect to physician, specialist, and laboratory practices and services.

Quality assurance can be given an extremely broad meaning. Since section 27(4)(g) is a permitted disclosure without any requirement for consent of the woman, I find that this subsection should not be given more expansive scope than the plain meaning of the provision. That means that there must be a standards or quality of care committee that has been established by the Agency and that committee must scrupulously follow the requirement in 27(4)(g)(i),(ii) and (iii). In any event, quality assurance activities are important, but the benefit to the specific patient may often be indirect since quality assurance may be focused on processes that benefit all patients and not any single woman.

It may be that the existing arrangement with the PPCC could be revised so that in the event of an opt-out, the PPCC would be denied access to that woman's data for purposes of the PPCC but it would still be available to the labs and her physician.

I am not persuaded that if any of the 300,000 Saskatchewan women in question choose not to be part of the PPCC that quality assurance of the entire program is substantially impaired. I recognize that in the view of the Agency this is counter to the principles of a comprehensive screening program. Our concern, of course, is compliance with HIPA and privacy 'best practices'. Presumably, the vast majority of Saskatchewan women would accept the value added by the PPCC Program and not choose to withdraw. On the other hand, being advised of an opt-out option may do some very positive things. It may enhance patient confidence in the screening program and would generate the other advantages that accrue to empowerment of Saskatchewan women.

XVIII A Discussion of Consent in HIPA (cont'd)

G. Position of the Agency on Possibility of Opt-out (cont'd)

It may encourage more dialogue between women and their family physician about cervical health, the importance of routine testing and prompt follow-up on abnormal results.

The education of the general public undertaken by the Agency and targeting under and over-screened sub-population groups and/or geographic regions may be adversely affected.

I expect that the education of the general public could proceed and assuming the great majority of women would choose not to opt-out, there would still presumably be valuable information to enable targeting of under and over-screened sub-population groups and/or geographic regions.

The review and adaptation of clinical practice guidelines to reflect evolving evidence of best practice may be adversely affected.

I expect that even if a small number of women should elect to opt-out there would be substantial evidence to enable the review and adaptation of clinical practice guidelines.

Presumably, through collaboration with the Saskatchewan College of Physicians and Surgeons that is responsible for professional standards of its members, guidelines can be reviewed and adapted regardless of whether a woman opts-out or not.

There would not be a centralized location for demographic information plus cytology reports plus histopathology reports for those women who choose to opt-out.

As noted earlier there can still be a database controlled by the regions so long as there is no "disclosure" of the data to the PPCC. My understanding is that information would be difficult to access through the laboratory information systems in the health regions. As they are presently operating, a family physician may still access some of that information albeit with difficulty.

XVIII A Discussion of Consent in HIPA (cont'd)

G. Position of the Agency on Possibility of Opt-out (cont'd)

A woman who opts out would find that cytotechnologists and pathologists and their clinical assessments could be much more difficult to be accessed by her family physician.

This concern again speaks to difficulty and inconvenience. I am advised by the Agency that cytological changes normally take place relatively slowly, and in terms of diagnostic practice, results and patterns over time are viewed as opposed to evaluating each cytology report as a separate and distinct event. Any woman who was considering an opt-out would need to understand these disadvantages that would accrue should she opt-out.

Women, who move within the province, switch providers or who have Pap tests done in a different part of the province from their current residence would find it is much more difficult for their cervical information to be aggregated.

I recognize there would be considerable difficulty in tracking women but I have seen no evidence that a significant number of women would likely meet both criteria of having opted-out and also moved within the province. In any event, women routinely move from one province to another and from one community to another within Saskatchewan and still presumably manage to get their health information, including laboratory test results from the former family physician forwarded to their new family physician. As a consequence of access to a provincial database with information on five years of Pap tests for any woman, the cytologist is able to meet the highest level of screening quality.

XVIII A Discussion of Consent in HIPA (cont'd)

G. Position of the Agency on Possibility of Opt-out (cont'd)

A woman who opts out may find that her family physician has more difficulty accessing cytology and histology reports for follow-up services.

I expect that the same problem would exist for other kinds of laboratory testing that a physician would have to try and aggregate from other providers and facilities in different parts of the province.

For a woman who opts out of the PPCC and then moves from Saskatchewan, there may be no follow-up through health care providers involved in the initial Pap test collection.

The previous comments would apply here too.

For a woman who opts out of the PPCC, there would presumably be no data entry services for electronically non-transferable cytology appended notes and non-transferable histology reports.

This may be a reason why a woman would be reluctant to opt-out.

For a woman who opts out of the PPCC, there would presumably be no manual data fixes for inaccurate health numbers and/or birthdates, nor manual fixes for data errors tracked to lab entry error and health care provider data errors.

I have seen no evidence as to what the incidence of such data errors is currently in this province.

XVIII A Discussion of Consent in HIPA (cont'd)

G. Position of the Agency on Possibility of Opt-out (cont'd)

> ***To allow opt-out would have a negative impact on breast cancer screening program. The reason is that to delete a woman's identity in the PPCC also deletes it from the Screening Program for Breast Cancer (SPBC) as it is a common client database. One database (SPBC and PPCC) means no duplication of work by running files for the same individual twice.***
>
> I am not clear why the system was designed without providing for an opt-out by a Saskatchewan woman in accordance with privacy best practices.

XIX The Health Research Experience

There has been considerable work done by the Canadian Institutes of Health Research (CIHR) on the question of consent. Although the PPCC, at least insofar as it operates at this time, involves diagnosis, treatment and care activities, I find that there are perhaps some useful lessons from the research community that can assist in identifying best practices. In particular, CIHR published a report in 2002 on a number of case studies involving the secondary use of personal information in health research.[141]

Case study #13 considered a study to identify the harmful health effects on women who received breast implants for cosmetic reasons over a 14 year period. The researchers publicized the study aims and methods at professional meetings, through women's interest groups, and in lay and scientific periodicals and newspapers. Informational pamphlets were also distributed to 35,000 physician offices across Canada for display in patient reception areas. A toll-free bilingual hotline was set up in order to provide more detailed information and to allow women to opt out of the research.

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[141] Secondary Use, supra, note 65

XIX THE HEALTH RESEARCH EXPERIENCE (CONT'D)

Case study #15 considered a registry of individuals who may have a genetic predisposition to colorectal cancer for the purpose of carrying out relevant research. This involved express written consent of the participants. Participation in the registry was voluntary and those who registered could withdraw at any point without jeopardizing their medical care.

Case study #16 considered a study of surveillance of cancer in neighbourhoods near the sources of pollution. It was "nearly impossible" to obtain informed consent given the sample size of 100,000 people, as well as the long latency period for potentially adverse health effects and the likelihood of relocation or death. Apparently there was no opt-out provision in the program it was determined "*beneficial to do a priori qualitative studies, utilizing focus groups representing individual citizens, interest groups, government agencies, other stakeholders and cancer patients, to better elucidate community concerns and interests. These focus groups to be interviewed prior to initiating the pilot study and facilitated by an independent behavioural scientist who will be identified through a competitive RFA process. The results of these consultations will be made public, also.*"[142]

In commenting on Case studies #13 and 16 the authors noted:

> "*For reasons elaborated above, obtaining express consent in the context of large studies on population health and/or health services can sometimes be impracticable to obtain. However this does not prevent researchers from seeking alternative means for providing individuals with the opportunity to become engaged and/or opt-out of the research. Researchers could also find creative ways of consulting relevant communities and studying representative focus groups with a view to better understanding what might be concerns of the larger study population that need to be addressed in research design.*"[143]

The CIHR report also states as follows:

> "*The case studies demonstrate the need for constructive, creative and innovative ways of respecting peoples' right to know and how to control how their information is used without necessarily requiring that express consent be obtained from every individual in every instance. The case studies demonstrate the need to develop appropriate alternatives to the traditional consent model, specifically for population health and health services research, taking into account the overall balance of risks and benefits both to individuals and society as a whole.*

[142] Ibid, page 109
[143] Ibid, page 29

XIX THE HEALTH RESEARCH EXPERIENCE (CONT'D)

These alternatives do not in any way abrogate the obligations to ensure, among other things, that:

- *An open, transparent and accountable process is implemented for managing privacy;*
- *The appropriate confidentiality agreements are in place binding users of the information; and,*
- *Effective safeguards are taken to protect the data against unauthorized disclosure."*[144]

There will certainly be a concern that allowing Saskatchewan women to fully opt-out will impair the utility of the PPCC. I would suggest that is unlikely to occur if women are provided with accurate, accessible information on the advantages of the PPCC including the convenience and quality assurance features and know that ultimately it will be their choice to participate or not.

XX PAN-CANADIAN HEALTH INFORMATION PRIVACY AND CONFIDENTIALITY FRAMEWORK

Is it relevant to consider national initiatives with respect to health information standards? The Saskatchewan government has in the past signalled the importance of national standards and the goal of harmonization of standards in Canadian jurisdictions.

On April 16, 2003, the current Minister of Health, in responding in Question Period observed as follows:

"...The bigger issue is how do we provide care in Canada with many, many provincial records into a national record? Mr. Speaker, we in Saskatchewan are at the forefront of working and developing a comprehensive health record. We have to make sure that everything that we do in our province fits in with a national plan and that we are going to continue working on that way with all of the partners in the system, rather than do some of the things that the members opposite want us to do."[145]

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[144] Ibid, page 9

[145] Saskatchewan *Hansard*, April 16, 2003, page 617

XX PAN-CANADIAN HEALTH INFORMATION PRIVACY AND CONFIDENTIALITY FRAMEWORK (CONT'D)

On April 21, 2003, the Minister in Question Period stated as follows:

> Hon. Mr. Nilson: -- *"Mr. Speaker, we are working on this challenging problem not only as part of the province of Saskatchewan but as part of the national program. The federal government has put in money for the Canada Health Infoway. We have been using some of that money. We've been putting our own money into a system which will ultimately result in an electronic health record which will hopefully prevent some more of these kinds of challenges.*
>
> *This is a very complex process. We have been working at it for ...very carefully and diligently. I guess what I would say is here in Saskatchewan we have done this very carefully to make sure that whatever we spend, we can keep using. I know our neighbours both to the west and to the east of us have had some substantial difficulties with their electronic health record projects. We in Saskatchewan are proud of the careful work that we've done."*[146]

Again on June 4, 2003, the Minister in Committee on Bill 28 observed as follows:

> *"I think the most interesting thing is, though, that we are working on national standards through the Canada Health Infoway operation. And Saskatchewan is actually Co-Chair with Canada in the development of many of the things that relate to health information in Canada. Because ultimately the goal is that you health information would be available if you are in a car accident in British Columbia, in a way that, for the specific purpose of treating you as a patient, you would be able to get back to your record in Saskatchewan."*[147]

In 1999 the federal Advisory Council on Health Infostructure produced its final report.[148] That report includes some thoughtful and far-sighted observations about the need for coordination and harmonization of health information and privacy regimes across Canada:

> *"Significant variations now exist in provincial and territorial laws, regulations and guidelines for privacy and the protection of personal health information in the public sector.*
>
> . . .

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[146] Ibid, page 655
[147] Saskatchewan *Hansard*, June 4, 2003; page 1438
[148] *Canada Health Infoway - Paths to Better Health*, Final Report; Minister of Public Works and Government Services, 1999

XX PAN-CANADIAN HEALTH INFORMATION PRIVACY AND CONFIDENTIALITY FRAMEWORK (CONT'D)

> *In the Council's view, as noted in its interim report, a real danger exists that Canada could end up with many different approaches to privacy and the protection of personal information. Different approaches could make it difficult, if not impossible, to improve the portability of services or create information resources needed for accountability and continuous feedback on factors affecting the health of Canadians. In some cases, any exchange of information might be prohibited by law in those jurisdictions that do not provide adequate protection for personal health information. Refusal to share information in such circumstances would be entirely defensible. However, it is to be hoped that the circumstances justifying such a refusal can be avoided in Canada.*
>
> *For these reasons, in its interim report the Council called on the federal Minister of Health to take the lead in encouraging an accord among provincial, territorial and federal governments to harmonize the approaches in their respective jurisdictions to privacy and the protection of personal health information taking into account best practices internationally. The Council also recommended that all government in Canada should ensure that they have legislation to address privacy protection specifically aimed at protecting personal health information through explicit and transparent mechanisms."*[149]

Subsequently, provincial, federal and territorial governments attempted to resolve a national standard by means of a document known as the *Harmonization Resolution*.[150] That document was not, however, acceptable to all governments and was never fully executed. More recently, Canadian governments have attempted to develop a *Pan-Canadian Health Information Privacy and Confidentiality Framework ("the Framework")*[151].

I understand that the Framework contemplates that it will serve as the basis for provinces to review and revise as necessary existing health information legislation to reflect the collection, use and disclosure rules in the Framework.[152] I further understand that the consent model employed in the draft Framework is one of implied consent.

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149 Ibid., page 5-2 and 5-3

150 Alberta Select Special Health Information Act Review Committee, verbatim dated June 1, 2004 at page HR-17; (available online at www.hiareview.assembly.ab.ca) (hereinafter "Alberta Select Special Health Information Act Review Committee") [hereinafter "Committee Debate"]

151 Ibid.

152 Ibid., page HR-20

XX PAN-CANADIAN HEALTH INFORMATION PRIVACY AND CONFIDENTIALITY FRAMEWORK (CONT'D)

The implied consent to the collection, use and disclosure of personal health information could be revoked by an individual. This implied consent approach has been taken by Ontario in its new *Personal Health Information Protection Act.*[153] ("PHIPA").

The consent provision in PHIPA is as follows:

> *18(1) If this Act or any other Act requires the consent of an individual for the collection, use or disclosure of personal health information by a health information custodian, the consent,*
>
> *(a) must be a consent of the individual;*
>
> *(b) must be knowledgeable;*
>
> *(c) must relate to the information; and*
>
> *(d) must not be obtained through deception or coercion.*
>
> *(2) Subject to subsection (3), a consent to the collection, use or disclosure of personal health information about an individual may be express or implied.*
>
> *(3) A consent to the disclosure of personal health information about an individual must be express and not implied, if,*
>
> *(a) a health information custodian makes the disclosure to a person that is not a health information custodian; or*
>
> *(b) a health information custodian makes the disclosure to another health information custodian and the disclosure is not for the purpose of providing health care or assisting in providing health care.*
>
> *(4) Subjection (3) does not apply to,*
>
> *(a) a disclosure pursuant to an implied consent described in subsection 20(4);*
>
> *(b) a disclosure pursuant to clause 32 (1)(b); or*
>
> *(c) a prescribed type of disclosure that does not include information about an individual's state of health.*

[153] S.O. 2004, c. 30

XX PAN-CANADIAN HEALTH INFORMATION PRIVACY AND CONFIDENTIALITY FRAMEWORK (CONT'D)

(5) A consent to the collection, use or disclosure of personal health information about an individual is knowledgeable if it is reasonable in the circumstances to believe that the individual knows,

(a) the purposes of the collection, use or disclosure, as the case may be; and

(b) that the individual may give or withhold consent.

(6) Unless it is not reasonable in the circumstances, it is reasonable to believe that an individual knows the purposes of the collection, use or disclosure of personal health information about the individual by a health information custodian if the custodian posts or makes readily available a notice describing the purposes where it is likely to come to the individual's attention or provides the individual with such a notice.

(7) A consent that an individual gives, before the day that subsection (1) comes into force, to a collection, use or disclosure of information that is personal health information is a valid consent if it meets the requirements of this Act for consent.

19(1) If an individual consents to have a health information custodian collect, use or disclose personal health information about the individual, the individual may withdraw the consent, whether the consent is express or implied, by providing notice to the health information custodian, but the withdrawal of the consent shall not have retroactive effect.

(2) If an individual places a condition on his or her consent to have a health information custodian collection, use or disclose personal health information about an individual, the condition is not effective to the extent that it purports to prohibit or restrict any recording of personal health information by a health information custodian that is required by law or by established standards of professional practice or institutional practice.

In the final report of the Alberta Select Special Health Information Act Review Committee, there is the following recommendation:

37 A committee of the Legislature should review consent requirements under the Health Information Act in early 2005 when the pan-Canadian health information privacy and confidentiality framework is finalized.

XX PAN-CANADIAN HEALTH INFORMATION PRIVACY AND CONFIDENTIALITY FRAMEWORK (CONT'D)

The discussion in that document that precedes the recommendation is as follows:

> *Under the Health Information Act, a custodian may collect, use and disclose individually identifying diagnostic, treatment and care information without the consent of the individual for care and treatment. This authority is subject to the overriding principles that restrict the flow of information: least amount of information and highest level of anonymity necessary for the purpose.*
>
> *The individual does not have the ability to consent or withdraw consent for disclosures of information required for care and treatment, although the custodian is required to consider the individual's expressed wishes in deciding how much information to disclose. The Act reflects the practice that was in place in the health sector at the time it was drafted.*
>
> *Since that time, the federal Personal Information Protection and Electronic Documents Act (PIPEDA) has come into effect and applies to custodians such as pharmacies, pharmacists and physicians in private practice. Under PIPEDA, Industry Canada indicates that informed consent is appropriate within the "circle of care". This differs from the approach in HIA described above. PIPEDA will apply unless the federal government exempts a province from the application of PIPEDA on the basis that the province has enacted legislation substantially similar to PIPEDA.*
>
> *Stakeholders were asked whether an informed knowledgeable implied consent model for disclosures for care and treatment is appropriate for Alberta's health system. A third of the stakeholders who commented supported the informed knowledgeable implied consent model, another third did not support the model, and the final third appeared to be in support but were somewhat equivocal.*
>
> *The Committee noted the matter of informed implied consent is central to the pan-Canadian health information privacy and confidentiality framework. Since the pan-Canadian framework is not yet finalized, the Committee was not in a position to address the matter of harmonization.*[154]

[154] Alberta Select Special Health Information Act Review Committee, Final Report, October 2004, page 32 (available online at www.hiareview.assembly.ab.ca)

XX PAN-CANADIAN HEALTH INFORMATION PRIVACY AND CONFIDENTIALITY FRAMEWORK (CONT'D)

There are at least three reasons for adopting the implied consent approach instead of the deemed consent now prescribed in section 27(2) of HIPA:

(1) Harmonization of the consent model and rules would promote common protection of health information for all Canadians.

(2) Canadian provinces have identified a common implied consent model as a key tactic to solidify their argument to exempt health organizations from the scope of PIPEDA.

(3) An interoperable electronic health record cannot easily be designed without common rules, particularly in the areas of consent for care and treatment. [155]

It is important to note that the Framework and Ontario's PHIPA are very recent developments in Canadian regulation of health privacy that have not been reflected or accounted for in Saskatchewan's HIPA.

XXI PERSONAL INFORMATION PROTECTION AND ELECTRONIC DOCUMENTS ACT

Since January 1, 2003, PIPEDA has applied to the collection, use and disclosure of personal health information in the province of Saskatchewan in the course of commercial activity. There is provision for a province to displace PIPEDA if it enacts legislation, either sectoral or general, that the federal Cabinet declares is "substantially similar". We are not aware of any initiative to have HIPA declared substantially similar to PIPEDA. Unless and until that happens health information trustees carrying on commercial activities in Saskatchewan are subject to both PIPEDA and HIPA simultaneously.

We should note that the Quebec Court of Appeal is currently considering the question of whether the government of Canada had the legislative competence to legislate private sector privacy in a province.

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[155] Committee Debate, supra, note 150, page HR-21

XXI PERSONAL INFORMATION PROTECTION AND ELECTRONIC DOCUMENTS ACT (CONT'D)

The Agency is not carrying on a commercial activity and hence is not subject to PIPEDA. Some actors in the health delivery arena in Saskatchewan must meet the requirements of PIPEDA. The relevant requirement is the consent requirement to collect, use and disclose personal health information. Industry Canada, the department responsible for administration of PIPEDA, issued a number of frequently asked questions under the title of PIPEDA Awareness Raising Tools in an attempt to address the apparent differences between health information rules permitting sanctioned sharing at the provincial level and PIPEDA. By virtue of articles #40, 41 and 42, there will be only a need for implied consent for the collection, use and disclosure of personal health information provided that an individual is given notice as to the policies and procedures of the organization.

To view and interpret section 27(2) of HIPA without any regard to these other developments would be short sighted.

XXII WHAT IS THE RISK OF NOT PROVIDING FOR OPT-OUT CONSENT?

Our office has identified two significant risks if no opt-out consent is provided:

(1) Saskatchewan women may become less willing to share information with their primary care providers and in some cases may be deterred from seeking appropriate and timely medical advice and Pap testing.

(2) A court may determine that section 27(2) of HIPA offends the Charter. Given the momentum described earlier in this Report in support of an implied (and revocable) consent for most collection, uses and disclosures evident in the Ontario PHIPA, the Framework and PIPEDA, it is questionable that HIPA's deemed consent or no- consent could meet all three criteria in the second part of the Oakes test. The court would then have limited options including striking down section 27(2) of HIPA.

XXII WHAT IS THE RISK OF NOT PROVIDING FOR OPT-OUT CONSENT? (CONT'D)

Section 33 of the Charter provides for a legislative override and is sometimes called the "Notwithstanding clause". This allows the Saskatchewan Legislative Assembly to expressly include in a law a declaration that the particular law will operate notwithstanding sections 2 and 7 to 15 of the Charter. Such an override provision expires after five years unless it is renewed by the Assembly. In any event, the Saskatchewan Legislative Assembly has not elected to invoke the notwithstanding clause in HIPA.

What do we do in such a case where there are serious and legitimate concerns that section 27(2) of HIPA offends sections 7 and 8 of the Charter and cannot be justified under section 1 of the Charter? I have determined that it is appropriate for me to recommend that the Legislative Assembly resolve the legal question as to whether section 27(2) of HIPA does or does not offend the Charter.

I note that there is a Saskatchewan vehicle ideally suited for such a purpose -- *The Constitutional Questions Act.*[156]

The Constitutional Questions Act provides in part as follows:

> *2. The Lieutenant Governor in Council may refer to the Court of Appeal for hearing and consideration any matter that he thinks fit, and the court shall thereupon hear and consider the matter.*

[156] *The Constitutional Questions Act*, R.S.S. 1978, c.C-29

XXIII CONCLUSION

Both my findings and my recommendations appear immediately after the Executive Summary.

Attached to this Report is a list of additional resources that this office has found useful in this investigation.

I am grateful for the excellent cooperation and assistance this office has received from officials in the Saskatchewan Cancer Agency and its solicitors, officials in the Saskatoon Regional Health Authority, Regina Qu'Appelle Regional Health Authority, Saskatchewan Health, the College of Physicians and Surgeons, the Saskatchewan Medical Association and from many Saskatchewan women.

Dated at Regina, in the Province of Saskatchewan, this 27th day of April, 2005.

R. Gary Dickson, Q.C.
Saskatchewan Information and Privacy Commissioner

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Appendix A

Resource Material

Texts and Reports

An Overview of The Health Information Protection Act. Saskatchewan Health, July 1999. [Available Online: http://www.health.gov.sk.ca/ph_br_health_leg_overhipa.pdf]

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APPENDIX A

RESOURCE MATERIAL

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RESOURCE MATERIAL

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APPENDIX A

RESOURCE MATERIAL

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Appendix A

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